ELECTROCARDIOGRAPH

ECG-1200G

MANUAL BOOK

Elitech® TECHNOVISION

Foreword

Please read the user manual carefully before using this product. The operating procedures specified in this user manual must be strictly followed. This manual describes abnormalities, and possible damage to the product or the user. See the following chapter for details. Failure to follow the user manual may result in abnormal measurements, damage to the Device, or personal injury. The manufacturer is not responsible for the safety, reality and performance issues of such results due to the user's failure to comply with this user guide for use, maintenance or storage. The free service and repair also doesn't cover those errors.

The content in this user guide corresponds to the original product. For Software improvements and some modifications, the content in this user guide is subject to change without prior notice, and we sincerely apologize for that.

Attention

Before using this product, the safety and effectiveness of the following should be considered:

- Protection against electric shock type: class I (AC power supply), internally powered equipment (power supplied by battery)
- Degree of protection against electric shock: CF type, defibrillation-resistant applied parts
- Working mode: equipment running continuously
- Enclosure protection class: IPX0
- Measurement results must be explained by a professional doctor combined with clinical symptoms.
- Reliability of use depends on whether the operating and maintenance instructions in this user manual are followed.
- Service life: 5 years.
- Date of manufacture: see label.
- Contraindications: none

⚠ **Warning: To ensure the safety and effectiveness of the Device, use accessories recommended by the company. Device maintenance and repair must be carried out by:**

personal professional determined by the company. Reinstalling the Device is prohibited.

Operator's responsibility

- The device must be operated by professionally trained medical staff, and stored by a dedicated person.
- The operator must read the User's Guide carefully before use, and strictly follow the operating procedures described in the User's Guide.
- Safety requirements have been fully considered in product design, but operators cannot ignore patient and Device observation.
- The operator is responsible for providing product usage information to the company.

Corporate responsibility

- The company supplies quality products to users according to company standards.
- The company installs and debugs equipment and trains doctors on a contract basis.
- The Company performs repair of the Device within the warranty period (one year) and maintenance services after the warranty period.
- The company responds timely to user reguest.

Statement

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Our company reserves the right to final explanation of this user guide, and reserves the right to change the contents of this user guide without prior notice, and reserves the right to change technology and product specifications.

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Chapter 1 Overview

1.1 Description

This product is a kind of electrocardiograph, which is capable of simultaneously sampling 12 leads of the ECG signal and printing the ECG waveform by thermal printing system. Its functions are as follows: record and display the ECG waveform in auto/manual mode; measuring ECG waveform parameters automatically, and automatic analysis; pacing ECG detection; prompt for electrode-off and out of paper; optional interface language (Chinese/English, etc.); built-in lithium battery, powered by AC or DC; Arbitrarily select lead rhythm to easily observe abnormal heart rate; case database management, etc.

1.2 Intended use

This product is suitable for hospitals, scientific research, wards, wards, ambulances and conducting medical consultations. It can be used by medical institutions to record human ECG signals, collect and extract ECG waveforms.

1.3 Main technical specifications

1.3.1 Environmental conditions

Operation:

a) Ambient temperature: +5℃ ~ +35℃
b) Relative humidity: 25%~95% (non-condensing)
c) Atmospheric pressure: 700 hPa ~ 1060 hPa
d) Power supply:
Voltage: AC: 100-240V~
Frequency: 50Hz, 60Hz
Input Power: ≤150VA
Battery: 14.8V, rechargeable lithium battery 5000 mAh

Transport and Storage:

a) Ambient temperature: -20 ℃ ~ +55 ℃
b) Relative humidity: ≤95%
c) Atmospheric pressure: 500hPa~1060hPa

1.3.2 Input way: defibrillation protection

1.3.3 Leads : Standard 12 leads

1.3.4 Patient leakage current: <10μA

1.3.5 Input Impedance: ≥2.5 MΩ

1.3.6 Frequency response:

Input amplitude value	Input frequency and waveform	Re relative output response
1.0	0.67Hz~40Hz, Sine wave	±10% [a]
0.5	40Hz~100Hz, Sine wave	+10%, -30% [a]
0.25	100Hz~150Hz, Sine wave	+10%, -30% [a]
0.5	150Hz~500Hz, Sine wave	+10%, -100% [a]
1.5	≤1Hz, 200ms, Triangle wave	+0%, -10% [b]
[a] Relative to 10Hz [b] Relative to 200ms		

1.3.7 Time constant: ≥3.2s

1.3.8 CMRR: >105 dB (plus filter)

1.3.9 Filters:

- Filter Frekuensi Daya AC : 50/60Hz
- Filter EMG : 25Hz, 30Hz, 35Hz, 40Hz, 45Hz
- Filter DFT : 0.05Hz, 0.5Hz, 1Hz, 0.15Hz, 0.25Hz, 0.32Hz
- Filter Low-pass : 75Hz, 100Hz, 150Hz

1.3.10 Recording method: Thermal printing system

1.3.11 Recording paper specifications: 210 mm(W)*20m(L) High-speed thermal paper

1.3.12 Paper Speed Selection : 5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s

1.3.13 Gain control (sensitivity): 1.25mm/mV, 2.5mm/mV, 5mm/mV, 10mm/mV, 20 mm/mV, 40mm/mV, 10/5mm/mV, 20/10mm/mV

1.3.14 Automatic record: record settings according to the format and automatic recording mode, automatically change leads, automatically measure and analyze.

1.3.15 Rhythm record: recording settings according to the rhythm recording format and mode, automatically measuring and analyzing.

1.3.16 Manual Record: record according to manual record format.

1.3.17 Measurement parameters: HR, PR interval, P duration, QRS duration, T duration, QT interval, Q-Tc, P axis, QRS axis, T axis, R(V5), S(V1), R(V5) + S(V1) amplitude.

1.3.18 Product safety type: Class I, Type CF, defibrillation resistant applied parts.

1.3.19 Polarization resistance voltage: ±610 mV

1.3.20 Noise level: ≤12μVp-p

1.3.21 ECG signal input sampling frequency: 32 kHz

1.3.22 Sampling frequency of wave data processing: 1kHz

1.3.23 Sampling precision: 24-bit

1.3.24 Minimum detection signal: 10Hz, 20μV (peak value) deflected sinusoidal signal can be detected.

1.3.25 Pacing detection channel: Standard II

1.3.26 Input signal accuracy: ±5%

1.3.27 Amplitude quantization: ≤5μV/LSB

1.3.28 Interchannel time deviation: <100 μs

1.3.29 Fuse specifications: 2pcsΦ5x20mm AC delay insurance: TI.6AL250V

1.3.30 Dimensions: 340mm(L)*320mm(W)*85mm(H)

1.3.31 Net weight: 3.2 kg

1.4 Main character

1.4.1 Display with 800*600dots, 8" high color resolution, running with touch screen or functional buttons which is easy and fast.

1.4.2 Synchronized collection for 12-lead ECG, using digital signal processing technology to perform AC filter, DFT filter and EMG filter on ECG signal, to obtain high quality ECG.

1.4.3 Displays an on-screen 3/6/12-lead ECG, and print mode, sensitivity, paper speed, filter status and other information that facilitates comparative diagnosis.

1.4.4 The device gets power from AC or DC (can adapt to AC 50/60Hz frequency), with built-in lithium battery and charging circuit, perfect battery overcurrent and overvoltage protection circuit.

1.4.5 Multiple printing modes and formats, including auto 12x1, 6x2+1(rhythm lead), 6x2, 3x4+2 (rhythm lead), rhythm 12, rhythm 10, rhythm 8, rhythm 6 and manual. The trend graph and histogram of the RR intervals

can be printed. The printed wavelength can be adjusted. With timed print function to meet various application requirements.

1.4.6 The rhythm leads can be chosen arbitrarily to facilitate the observation of abnormal heart beats.

1.4.7 Clinical information such as patient name, gender, age, sampling method, and department can be entered.

1.4.8 Built-in large-capacity memory, makes it easy for doctors to review medical records and statistical information.

1.4.9 Multi-language interface and reports (Chinese, English, Turkish, Portuguese, German, Russian, Kazakh, etc.).

1.5 Software Overview

Software Name: ECG1200G embedded software
Software Specifications: none
Software Version: V1.6.1
Version naming rules: V<major version number>. <minor version number>. <revised version number> Software version can be found in " About ".
Algorithms involved:
Name: ECG algorithm
Type: mature algorithm
Use: to convert the human body ECG signal into an intuitive waveform image and then analyze.
Clinical function: Electrocardiogram is an important method for clinical diagnosis of cardiovascular disease. How to use a computer to analyze ECG quickly, automatically and accurately has become a hot topic for scholars at home and abroad. The ECG algorithm is the key to the analysis and diagnosis of ECG signals, and its accuracy and reliability determine the effectiveness of the diagnosis and treatment of patients with heart disease.

Chapter 2 Safety Precautions

2.1 Make sure the Device is placed on a flat workbench. Avoid strong vibration or impact when moving it.

2.2 When working with AC power, the power cord must be 3-core, the rated frequency and voltage of the AC power supply must match the identification in the manual and have sufficient capacity. If the supplied three-core power cord cannot be used, use the internal DC power supply or replace the three-core power cord that meets the standard requirements.

2.3 A perfect power supply system and grounding is required indoors.

2.4 If there is a question about the integrity of the protective earth wire or the reliability of the connection of the protective earth wire cannot be guaranteed, the Device must be run on the built-in DC power supply.

2.5 Safety requirements have been fully considered in product design, but operators cannot ignore patient and Device observation. Turn off the power or remove the electrodes if necessary to ensure patient safety.

2.6 Please turn off the Device and unplug the power cord before changing the fuse or cleaning and disinfection. Do not rub the screen with sharp materials.

2.7 Keep the Device away from water, do not use or store in a place with high air pressure, humidity or temperature above standard, poor ventilation, or too much dust.

2.8 Do not use the Device in areas with flammable anesthetic gases or other flammable chemicals, otherwise there is a danger of explosion or fire.

2.9 Do not use the Device in a medical hyperbaric oxygen chamber, unless there is a danger of explosion or fire.

2.10 This device is not intended to act directly on the human heart. If this Device is used with a cardiac defibrillator or other electrical stimulation Device at the same time, disposable electrodes and an ECG lead cable with a defibrillation function must be selected. It is better not to use this Device with other electrical stimulation Devices at the same time. If necessary, there should be a professional technician guiding on the scene, and the selected accessories should be appointed by our company

2.11 When the electrocardiograph is used in conjunction with a high-frequency electric scalpel, the ECG electrodes must be kept away from the

contact of the electric scalpel to prevent burning of the electrode wires caused by high-frequency sparks.

2.12 When the electrocardiograph is used in conjunction with a defibrillator, the operator should avoid contact with the patient or the bed. The defibrillation electrodes must not directly touch the ECG electrodes to prevent sparks from burning the Device and the patient.

2.13 Please do not use the electrocardiograph in an environment disturbed by high-power Devices such as high-voltage cables, X-rays, ultrasonic and electrical machines, keep the Device away from emission sources such as mobile phones.

2.14 If other equipment is connected to this ECG Apparatus, it must be a Class I Apparatus compliant with IEC60601-1. Since the total leakage current can injure the patient, leakage current monitoring is carried out and taken over by the connected equipment.

2.15 EMC related notes

The device complies with the safety standards for medical electrical equipment or system electromagnetic compatibility in IEC60601-1-2. Electromagnetic environments exceeding the IEC60601-1-2 standard may cause harmful interference to the Device or prevent the Device from performing its intended function or reduce its performance. Therefore, if there is a phenomenon that is not in accordance with its function when used, be sure to confirm and eliminate side effects before continuing to use it. The appropriate precautions for this situation are given in this manual.

- The Device or system must not be used in close proximity to or stacked with other Devices. If it is to be used in close proximity to or stacked with other Devices, it shall be observed and verified that the Device functions normally under the configuration in which it is used.
- Use of ACCESSORIES other than those specified by the MANUFACTURER of the Device or system, may result in an increase in EMISSIONS or a decrease in the ME IMMUNEITY OF THE EQUIPMENT or ME SYSTEM.
- Effects of radiated electromagnetic waves: Use of mobile phones may affect the operation of the Device. When installing medical electrical equipment, be sure to remind people around the device to turn off mobile phones and small radios.

- Effects of electromagnetic shock and conduction waves: High-frequency sound from other equipment may enter the Device through the AC socket. Please identify the noise source, if possible, stop using the equipment. If the equipment cannot be disabled, use noise-canceling equipment or take other measures to reduce its impact.
- Effects of static electricity: Static electricity in a dry environment (indoor) may affect the operation of the Device, especially in winter. Before using the Device, humidify the indoor air or discharge static electricity from the cable and operator.
- Effects of thunder and lightning: If there is thunder and lightning in the vicinity, it may cause voltage spikes in the Device. If you are concerned about a hazard, disconnect the AC power and use the internal power supply.

2.16 Notes on ECG waveform measurement and analysis.

2.16.1 Identification of P waves and Q waves is not always reliable with intensive EMG or AC interference. Similarly, ST segment and T waves with baseline deviation.

2.16.2 The winding and the unclear position of the ends of the S and T waves can cause errors in measurement.

2.16.3 When the R wave is not checked due to multiple loose leads or a low voltage QRS wave, the heart rate measurement can deviate greatly from the correct one.

2.16.4 In the case of low voltage QRS, calculation of the ECG axis and identification of the QRS wave boundary point is not always reliable.

2.16.5 Occasionally, a frequent ventricular premature complex can be identified as the dominant beat.

2.16.6 The incorporation of versatile arrhythmias can result in unreliable measurements because of the difficulty in distinguishing the P waves in such situations.

2.16.7 device has an automatic analysis function which automatically analyzes the obtained ECG waveforms without reflecting all patient status. The results of the analysis sometimes do not match the doctor's diagnosis. Therefore, the final conclusion needs to be analyzed comprehensively by the doctor combined with the results of the analysis, clinical characterization of the patient and the results of other tests.

Chapter 3 Warranty

3.1 Under normal use, under strict observance of user manuals and operating records, in case of failure, please contact our customer service department. Our company has sales records and customer records for each Device. Customers have two years free warranty service from the date of delivery according to the following conditions. In order to provide you with a thorough and fast maintenance service, please send us a maintenance card in time.

3.2 Our company can adopt ways such as guidance, prompt service to the company or door-to-door service, etc. to carry out the warranty promise.

3.3 Even within the warranty period, the following repairs are chargeable.

3.3.1 Errors or injuries caused by misuse that are not in accordance with the user manual and operating records.

3.3.2 Mistakes or injuries caused by accidental falls after purchase.

3.3.3 Errors or injuries caused by repair, reconstruction, decay, etc. Not by our company.

3.3.4 Errors or injuries caused by improper storage or force majeure after purchase.

3.3.5 Error or injury caused by improper use of thermal recording paper.

3.4 The warranty period for accessories and spare parts is half a year. Power cord, recording paper, operating manual and packing materials are not included.

3.5 Our company is not responsible for any other connected Device error caused by this Device fault directly or indirectly.

3.6 The warranty will be void if we find the protection label has been destroyed.

3.7 For maintenance costs beyond the warranty period, our company recommends continuing to use the "Maintenance contract rules". Please refer to our customer service department for details.

Chapter 4 Working Principles and Structural Characteristics

4.1 Working principle and block diagram

4.1.1 Power supply unit

1) Power supply principle

The switching power supply provides +24V working voltage to the thermal printer head, provides a limiting constant current voltage for charging lithium batteries in Devices with DC-DC circuits, and generates +5V and +12V voltages through the power conversion to supply power to the same module. in accordance. At the same time, the lithium battery in the Device can independently meet the working requirements of each module in the Device through the buck-boost circuit.

2) The principle block diagram is shown in Figure 4.1

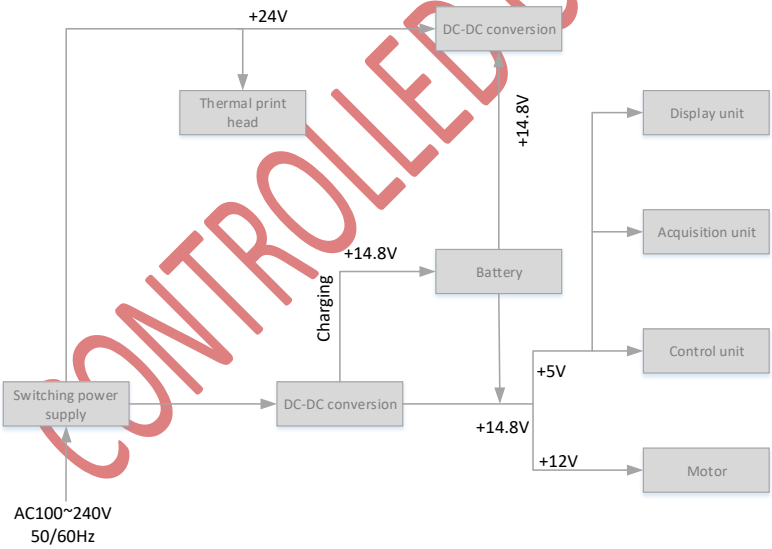


Figure 4-1 Power principle block diagram

⚠ **Note: Principle block diagrams and component lists are only available to service stations or maintenance personnel designated by our company.**

4.1.2 Signal acquisition unit

The signal acquisition unit uses a floating arrangement, which is a signal acquisition and processing system, including an analog circuitry section and A/D conversion (with 24 bits sampling accuracy) and a data processing section. The analog circuit consists of the following signal, amplification, anti-aliasing low-pass filtering, lead-off detection and overload detection. The CPU system is responsible for coordinating the work of each circuit such as the A/D converter, lead-off detection circuit and overload detection circuit, to achieve signal acquisition, processing and lead-off detection. The control and A/D conversion and data acquisition information between the floating circuit and the solid circuit is transmitted through the optoelectronic coupler.

4.1.3 Control unit

a) Principle of control unit

The control system consists of a printing system, a button system, a liquid crystal display system and a signal acquisition system. The ECG signal sent from the signal acquisition system through the high-speed optoelectronic coupler is received by the CPU system, after digital filtering, gain adjustment and motor drive, is sent to the printing system to print the ECG waveform. After printing is complete, the CPU system processes waveform measurement and analysis. The CPU system also receives the interrupt signal and key code from the key system to complete the interrupt processing. In addition, the lead-off signal, paper-out detection, battery voltage management, and automatic power-off are also managed by the CPU system. The liquid crystal display system receives data and comments from the CPU system to complete the Device control status display.

b) The principle block diagram is shown in Figure 4-2

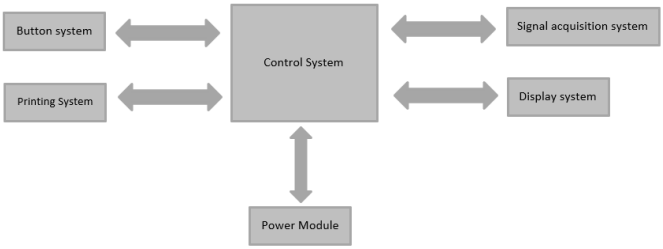


Figure 4-2 Control unit block diagram

4.2 The name of each part and its function

4.2.1 Front look

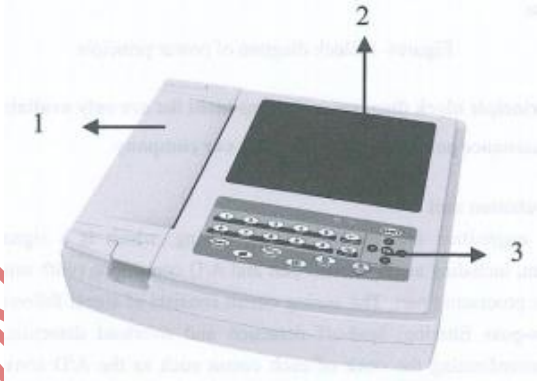


Figure 4-3 Front view

1) Paper compartment
   Close the paper compartment, holding the printing paper.
2) Screen display
   Displays the patient's ECG and related information.
3) Button area
   Control Device operation, and enter information.

⚠ **Notes**

⚠ **Do not place heavy objects on the screen or hit them, otherwise the screen will be damaged.**

⚠ **When the Device is not in use, cover it to prevent liquid spilling on the screen.**

⚠ **Do not use sharp objects to operate the buttons, otherwise it may cause permanent damage to the buttons.**

4.2.2 Side view

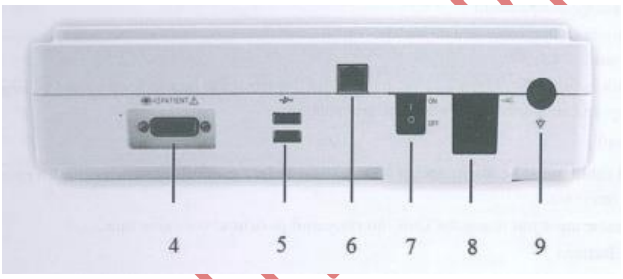


Figure 4-4 Side View

4) Lead cable interface
Connect with lead cable.

5) USB interface
Communicating with computers. ECG data and analysis results can be transmitted to the computer, using the computer, many functions can be achieved, such as archiving, managing and analyzing ECG data, which facilitates clinical research, organizational teaching and training, as well as program improvement, case import and export, and connection with an external printer.

6) Network Interface
Connect with LAN, then perform remote and case analysis by LAN experts .

7) Main Power Switch
Control Button is connected with AC power.

8) Input Socket

Connect with AC power cord.

9) Equipotential Terminal
Connected with potential equalization conductor.

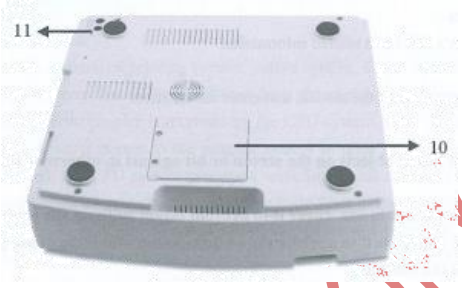


Figure 4-5 Bottom View

10) Battery Case
Built -in rechargeable battery.

11) Fuse
Built-in Fuse Rod, T1.6A L250V. It can keep away the damage to human body by high voltage and high current by polluting tissue.

⚠ **Notes**

a. lead cable must be disconnected from the patient before connecting with the computer via the USB interface.

b. The operator should not touch the USB interface and the patient at the same time.

4.2.3 Knob

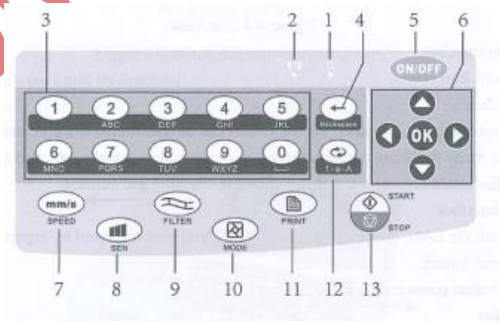
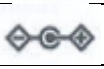


Figure 4-6 Schematic diagram of the Button

1) Startup indicator
   It glows green after turning on the Device.
2) Power status indicator
   Green indicates that the AC power supply is in use. At this time, there is no battery in the Device or the battery is full. Two colors red and green indicate that the battery is charging.
3) Number Keys
   Input patient information, hospital name, bed number and other information, supports Chinese and English.
4) Backspace
   Change the entered information, long press can clear the title.
5) ON/OFF
   When the Device is powered on, short press this button, it will ask whether to turn off the Device, long press this button to turn off the Device.
6) Direction Key
   Including up, down, right, left and OK buttons, quick and easy.
7) SPEED
   Change ECG recording speed
8) SEN
   Adjust the sensitivity manually.
9) FILTER
   Set filter mode.
10) MODE
    When the Device is in the sampling interface, use the MODE button to select the print mode.
11) PRINT
    Print a sample ECG waveform or finish printing.
12) Switch input method button
    Under input status, use these keys to switch between numbers, lowercase, uppercase, and symbols.
13) Input method setting button
    Collect ECG waveforms and set display mode.

4.2.4 Symbol

~ AC	AC working mode
OFF	Alternating Current -- OFF
ON	Alternating Current -- ON
	equipotential point
	Places need attention, please refer to the user manual
	CF applied art type, with defibrillation - proof function
	USB interface
◀ PATIENT	Lead cable socket
FUSE T1.6AL250V	Fuse Specifications
	Serial number
	Manufacturer
	Manufacturer date
	Batch code
	latex free
	Atmospheric pressure limit
	Temperature limitation
	Moisture limitation

	Indoor use
	Polarity of DC power connection
	Waste disposal symbol. This symbol indicates that waste electrical and electronic equipment cannot be disposed of as unsorted municipal waste and must be recycled separately.
	This way
	Fragile, handle with care
	Keep away from rain
	Stacking limit by number
	See instruction manual/booklet.
	This item complies with Medical Device Directive 93/42/EEC of 14 June 1993, European Economic Community directive.
	Catalog Number.
	Authorization of representatives in the European Community.
	General warning sign. C note: Background color: Yellow Triangle ribbon: Black

Chapter 5 Operational Precautions

5.1 Precautions before use

5.1.1 For safe and effective use, please read the user manual carefully before operation.

5.1.2 Check to make sure that the Device is in good condition.

5.1.3 The device must be placed on a flat surface, and move gently to avoid strong vibrations or shocks

5.1.4 Check to make sure that the main cable is connected properly, and that the device is properly grounded.

5.1.5 The AC frequency and voltage must meet the requirements, and sufficient current capacity must be guaranteed.

5.1.6 When using the battery for power supply, check to make sure that the battery voltage and battery status are in good condition, and that the battery has sufficient charge.

5.1.7 When the Device is used in conjunction with other equipment, all Device and equipment must be equipotentially grounded to protect the user and operator.

5.1.8 Install the Device in an easily grounded area in the room. Do not allow the lead wires and electrodes connected to the patient and patient to come into contact with other parts of the conductor, including earth or hospital beds.

5.1.9 Clean the lead wires with neutral solvent. Do not use alcohol or gemicide based cleaners.

5.1.10 Ensure that the Device operates within the normal ambient temperature range from 5°C to 40°C. If the Device is stored at a higher or lower temperature, leave it in the operating environment for at least 10 minutes before use to ensure normal functioning.

5.2 Precautions during operation

5.2.1 Printing can begin once the ECG waveform stabilizes.

5.2.2 During use, the doctor should observe the patient carefully and cannot leave the operation site. If necessary, turn off the power or remove the electrodes to ensure patient safety.

5.2.3 The patient and the device can only be connected via lead wires through the electrodes, to avoid the patient touching other parts of the device or conductors.

5.2.4 The patient cannot move during the operation.

5.2.5 Maintenance or repair of the Device or accessories is not permitted during use.

5.3 Precautions after use

5.3.1 Set the state of all functions to initial state.

5.3.2 Disconnect the power, gently remove the electrode and limb clip, then remove the lead wire, do not pull it by force.

5.3.3 Clean the Device and all accessories, and save it for future use.

Chapter 6 Preparations Before Surgery

6.1 Recording paper installation

6.1.1 This device adopts high-speed recording paper, the specification is 210 mm(W)x20 m(L).

6.1.2 How to install the recording paper is explained as follows:

1) As shown in Figure 6-1, use both hands to open both sides of the paper tray cover at the same time to open it. Take out the roll, load it on the paper roll as shown in the picture. The side of the paper with the grid should be facing down, then snap it into the proper position in the paper holder.

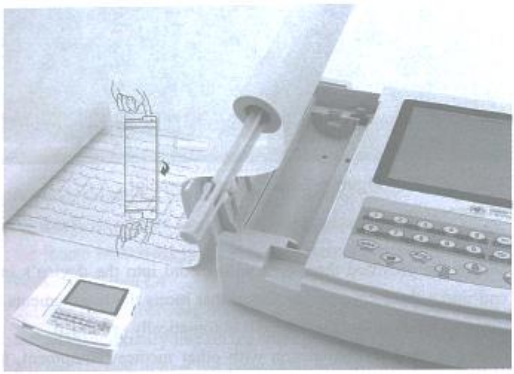


Figure 6-1 Installation of recording paper

2) Pull the recording paper out of the paper tray cover slot, and close the cover.

⚠ **Notes**

⚠ **When opening the paper holder cover, it is not recommended to open with separate sides, otherwise the operation of the equipment will be affected.**

⚠ **The recording paper should line up with the slots of the paper cabinet cover. It is recommended to leave 2 cm paper outside.**

6.1.3 If the recording paper runs out during recording, the Device will stop printing automatically, and the screen will display a paper shortage warning, as shown in Figure 6-2.

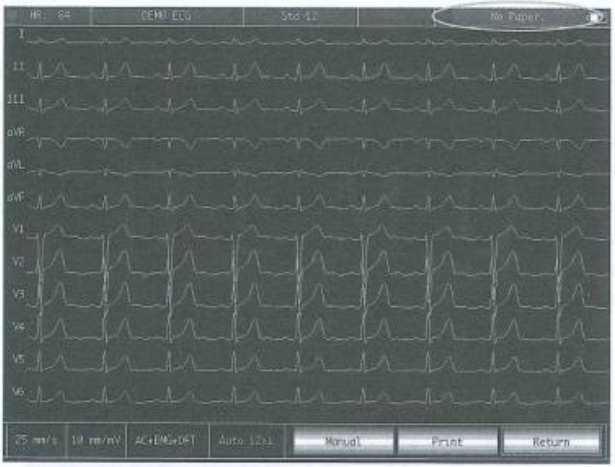


Figure 6-2 Lack of paper demand

6.2 Power supply connection

6.2.1 air conditioning

Insert one end of the supplied three-core power cable into the Device's input jack, and insert the other end into a qualified three-core power socket. Make sure the connection is secure and reliable, and the Device is grounded automatically.

When the Device is used in conjunction with other medical equipment, use the supplied potential equalization cable to connect the equipotential terminal of the Device to the equipotential terminal of the connected equipment to prevent leakage current and protect the Device.

6.2.2 Battery

The device has a rechargeable lithium battery, which does not need to be reinstalled by the user. Check the power and battery status before use.

⚠ **Note: Connect one end of the potential equalization cable to the equipotential terminal of the Device , and connect the other end to earth to increase the reliability of the earth . Do not use other pipes as ground wires, otherwise the patient may be in danger of electric shock.**

6.3 Lead cable connection

Connect the main cable to the main cable interface on the Device, and secure it to the Device with mounting knobs on both sides of the main cable to prevent poor connection and affect detection.

⚠ **Note: The main cable interface cannot be used for any other purpose except as an ECG signal input interface.**

6.4 Electrode installation

Correct electrode placement is an important part of accurately recording an electrocardiogram. Make sure the electrodes are in good contact. Old electrodes and new electrodes or reusable electrodes and disposable electrodes cannot be used at the same time. If different types of electrodes are used together, it will greatly affect the ECG recording. The electrodes or plug leads must not touch the surface or conductors of other objects, such as metallic coatings. Please replace everything when updating electrodes.

6.4.1 Chest Electrodes

As shown in Figure 6-3:

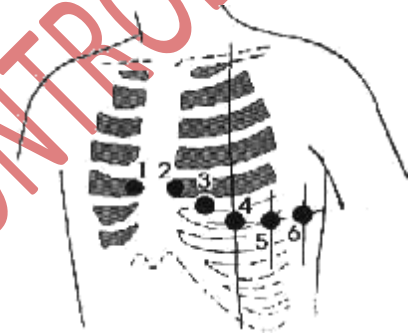


Figure 6-3 Installation of chest electrodes

The chest electrode must be attached to the following parts:
Cl (V1) : fourth intercostal space at the right sternal edge
C2 (V2) : fourth intercostal space at the left sternal margin

C3 (V3) : between C2 and C4
C4 (V4) : the intersection of the midclavicular line and the fifth intercostal space
C5 (V5) : left anterior axillary line in the same plane as C4
C6 (V6) : left midaxillary line in the same plane as C4
Clean the skin of the chest where the electrodes are to be attached with alcohol, and apply the sonie conductive paste to this skin (diameter range is about 25 nun) and the edges of the suction cup of the chest electrodes. Squeeze the suction ball to attach the chest electrode in the Cl-C6 position.

⚠ **Note: The conductive paste layers must be separated from each other, and the chest electrodes must not touch each other to avoid short circuit**
⚠ **Note: Please use qualified conductive paste to avoid skin damage**

6.4.2 Limbs Electrodes

Leg electrodes should be placed on the soft skin of the hands and feet. Before connecting, clean the skin of the electrode installation area with alcohol, then apply a small amount of conductive paste on the cleaned skin. The limb electrode connections are shown in Figure 6-4.

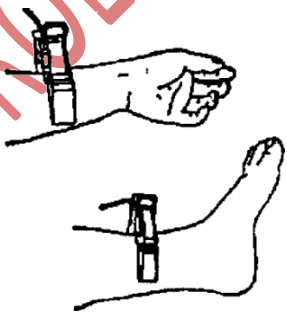


Figure 6-4 Installation of extremity electrodes

6.4.3 Lead wire color

Notes: In practical use, if the electrode markings do not match the markings described in the user manual, please follow the European/American standards in the table below to use. The

correspondence of the electrodes in each standard is shown in Table 6-1.

Table 6-1 Colors of lead wires.

Electrode Position	European Standard		American Standard	
	Tag	Color	Tag	Color
Right Arm	R	Red	Ra	White _
Left Arm	L	Yellow	La	Black
Left Foot	F	H Green	LI	Red
Right Foot	N/Rf	Black	Rl	H Green
1 Chest	C1	Red	V1	Red
Chest 2	C2	Yellow	V2	Yellow
Chest 3	C3	H Green	V3	H Green
Chest 4	C4	Chocolate	V4	Blue
Chest 5	C6	Black	V5	Orange
Chest 6	C6	Purple	V6	Purple

⚠ **Notes:**

- **It is recommended to install the main cable after turning off the Device.**
- **Apply an appropriate amount of conductive paste on the electrodes when attaching the electrodes.**
- **If the ECG waveform does not appear for a long time, check that the electrodes are in good contact with the skin.**

6.4.4 Prospect method and system

As shown in Figure 6-5

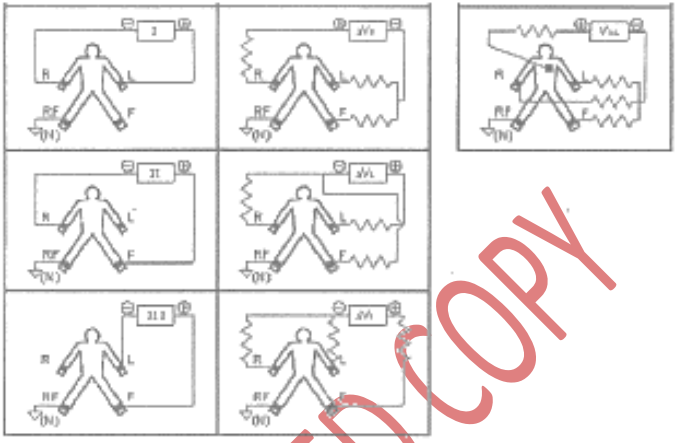


Figure 6-5 Lead System

6.4.5 Lead-off and overload indication

The device can check the connection status of the leads at any time. If a lead-off or overload is detected, the display will display the corresponding lead code in the upper left corner.

⚠ **Notes**

- **In the initial prompt area, red fonts represent start, yellow fonts represent excess.**
- **When the connection between the lead wire and the patient/Device is unreliable, and the ECG signal cannot be transmitted properly, the Device will display a lead-off.**

Chapter 7 Operating Instructions and Setting Parameters er

7.1 Main Interface

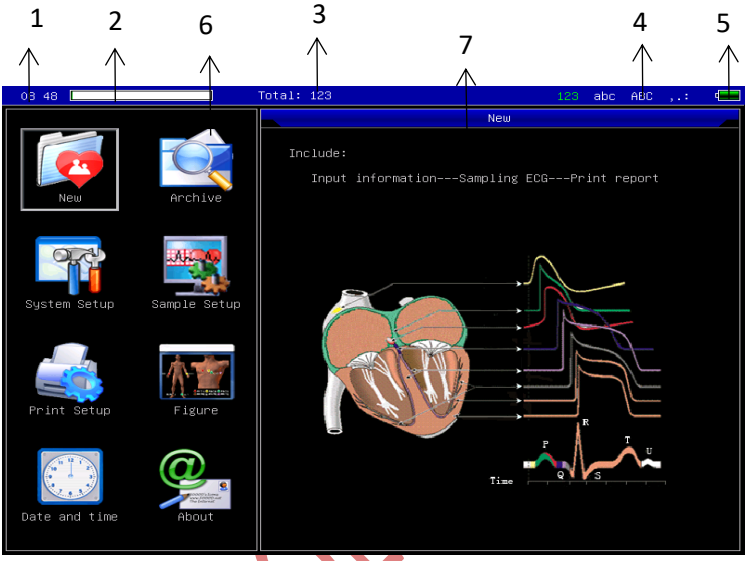


Figure 7-1

Status Bar

1. Time

   The time can be set in 

, so the detailed ECG recording time can be recorded.
2. Memory in use

   Instantly displays memory capacity according to actual usage. The green part shows the memory usage, the white part shows the remaining memory.
3. Number of cases stored in memory
4. Input method indicator

The current input method is marked in green. Use the buttons 

to change the input method.

5. Battery level (see 9.1)
6. Functional panels:

Select test view. When the instrument starts up, this operation will automatically start

Select archive management view, help, modify, or delete archive information

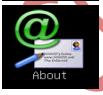
Choose to view a map sketch for electrode placement

Time and date setting

System settings

Sampling setting (test)

Printing settings, set printing mode, style and content



About us, displays information about our company and software version

Quick selection: use this button 
on the keyboard for quick selection on the functional module, after selecting, press the button 

to select the selected menu.

Quick setup: click on the functional module on the screen for a quick setup for the appropriate function.

7. friendly tips

7.2 Sampling Interface

Click 

on the main interface or  press the button to enter the sampling interface.

Note: There is case input time in system settings, therefore, case information must be entered before formal sampling. (see 7.3 for details).

The sampling interface provides multiple lead display modes, including 1-lead, 3-lead, 6-lead and 12-lead. The following image uses 12-leads as an example:

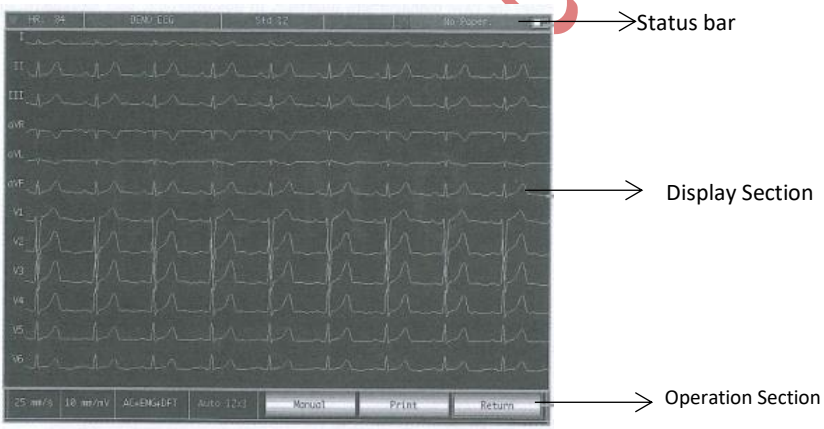


Figure 7-2

Status bar

1. HR: current sample heart rate value
2. Lead-off and overload: in demo mode, displays “DEMO ECG”. In sampling mode, displays the status of detected leads. The red lead icon indicates the lead-off. Yellow lead icon indicates overload.

3. Std 12: shows the sampling method. Prior to sampling, the sampling method can be set in the input patient information dialog box, settings including standard 12-lead, additional 6-lead, and standard 12-lead+additional 6-lead.
4. System status indicator:

Show content	Explanation
Process …	In the process of printing
Wait …	In the process of ending printing
No Paper .	Lack of paper, the user must restart the operation after filling the paper.
Print Timeout .	The connection between the system and the printing sub-system is broken.
ECG Timeout	The connection between the sampling system and sub-system is severed.
Low Power!	Low power, the system cannot start a print job.
No USB device	No external printer connected, user must restart printing after connecting with external printer.
Gather Time Less	Sampling time is not enough, printing will start after reaching the required time.

Display Section

The screen shows a 12-lead sample wave, by double-clicking on a wave, you can change between 1-lead, 3-lead, 6-lead and 12-lead.

Operations Section

Sets the print display via the appropriate operation settings.

1. Speed: use the buttons 

to change the speed between 5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, and 50 mm/s.
2. Gain (sensitivity): use the buttons  to change the gain between 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV and 40

mm/mV. The overall gain (sensitivity) can be checked with the calibration function.

3. Filter: use the button  to change the filter between NONE, AC, EMG, AC+EMG, DFT, AC+DFT, EMG+DFT and AC+EMG+DFT. Where,

AC	filter AC
EMG	Filters EMG
DFT	Filter

4. Print Mode: in the print settings, when the data type is set to "After Print", use the button  to switch the print mode between Manual, Auto 12x1, Auto 6x2+1, Auto 6x1+1_H, Auto 6x2, Auto 6x2_H, Auto 3x4+1, Auto 3x4+2 , Auto 1x12 , Rhythm 12 , Rhythm 10, Rhythm 8 and Rhythm 6 .

5. Print/End Print: use buttons  to start and stop printing operations.
    1) Auto mode: after starting printing, the system automatically prints and stores the 12-lead waveform in real time. The length is determined by the relevant setting in the print settings. According to the settings, automatic analysis data and conclusions are printed, and automatically stop printing.
    2) Manual mode: after starting printing, user needs lead setting to print waveform of different leads, asynchronous ECG printed by manual mode way and data is not saved. The user must press the PRINT button when printing is stopped.
    3) If a lead-off occurs during the sampling process, the printed waveform will be marked by "*".
    4) If lead overload occurs during the sampling process, the printed waveform will be marked by "+".

6. During the sampling process, press the PRINT button and wait for the printing to finish, a dialog box will appear including “Delete check box”, “Review”, “OK” and a prompt (if a lead-off or overload occurs during the sampling process, a prompt will appear on the dialog box).
7. End Sampling: after the Device has started sampling, use the button  to end sampling, and return to the main interface.

7.3 Case Information Input Interface

The case information input dialog box is shown below:

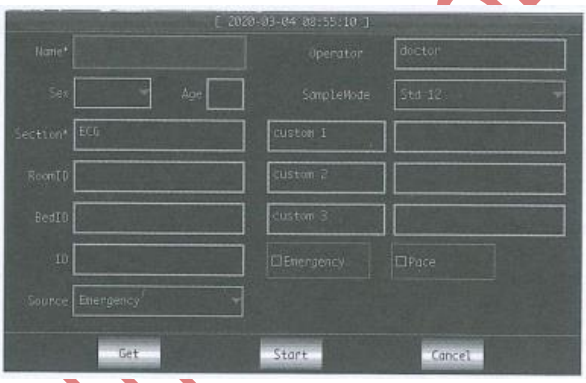


Figure 7-3

Select “Get” to get the last 10 patient information. For the same patient information, selecting it can add an edit box. Costume content can be adjusted according to your needs.

“*” indicates required content, can be set after entering password in “Servicing” in System Setup (initial password 888888).

After selecting the edit box, pressing the key 

will bring up the soft keyboard shown as below. Press “CN” or “EN” to choose between Chinese and English. Press “Caps” to switch between numbers, lowercase letters,

capital letters and symbols. “Space” is the space key, press to enter a space; “Backspace” is the backspace key, press to delete the last character entered. Click “OK” to confirm the input and exit the interface.

Figure 7-4

The keyboard may have input restrictions according to content restrictions. The restricted button will be grayed out and unavailable, as shown below:

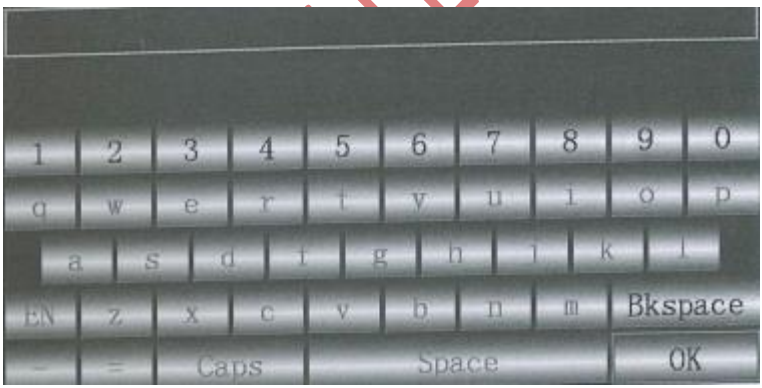


Figure 7-5

In addition, you can use the number buttons on the control panel to edit, and press the buttons 

to change between numbers, lowercase, capital

letters and symbols. Press the button 

to delete the last character entered. According to content restrictions, the selected input method is shown in green when switching input methods, and the restricted input method is grayed out and unavailable.

7.4 Case Management

On the main interface, click 

to enter the case management interface, as shown below:

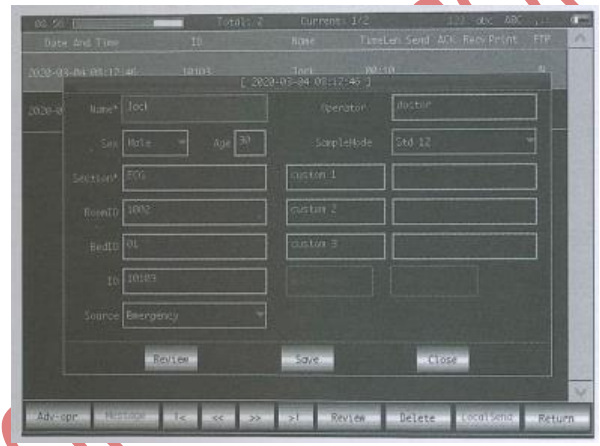


Figure 7-6

The interface above shows all the medical records stored on the device. Users can search for important cases with the query function on the interface (see 7.4.1), modify or delete case information with the edit function, and review stored case information (see 7.4.2).

Click 

to jump to the first page of the case list.

Click 

to jump to the last page of the case list.

Click 

to jump to the previous page.

Click 

to jump to the next page

In the operation section, “Adz-opr” contains menus from “list ALL” “Query” “Export ECG” and “Return”.

“Export ECG”: export the case in Device to U-disk by passing USB interface. The export path can be defined by yourself (symbols such as “\ / : ? < > |” are not included), the file types displayed are as below:

1) JPEG, BMP: report formats.
2) aECG: case data compliant with the HL7 standard.
3) DAT: case data, self-defined format.

“Query”: see 7.4.1

7.4.1 Query

Click “Query” in the “Adv-opr” settings to enter the query interface shown below. Enter the query conditions and click "Select" to get the desired results. After clicking “Clear”, the system will clear all the entered query conditions.

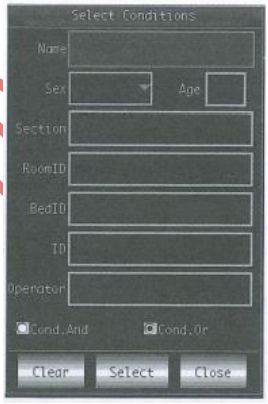


Figure 7-7

“Cond.And” and “Cond.Or” indicate the match mode of the query condition. You can choose one of the two. If you select “Cond.And”, the query result display will satisfy all input conditions at the same time; if you select

"Cond.Or", the query result display is only needed to meet the conditions entered.

Suggestion: when there are many cases, it is better to enter accurate query conditions and select "Cond.And" to quickly find cases.

7.4.2 Review

In the case management interface, select the case to review, click " Review " to enter the following dialog box, which displays the case information. Users are allowed to change patient information, after clicking " Save ", the information will be changed. Please note that modifications cannot be changed.

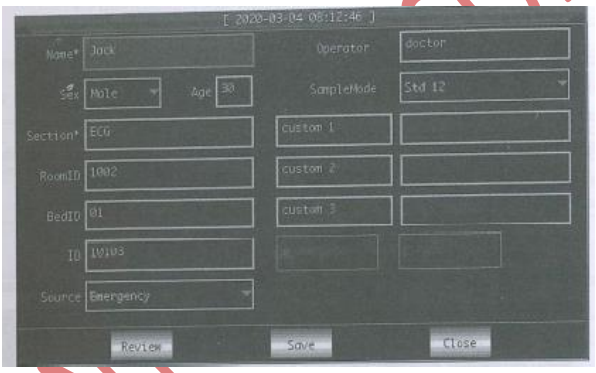


Figure 7-8

Make sure the input information is correct, click " Review " to enter the review interface, which is similar to the sampling interface.

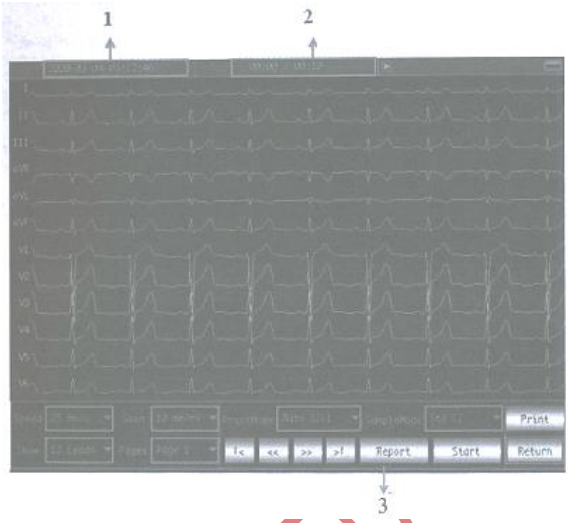


Figure 7-9

Status bar

1. It shows the detailed examination time of the case under review.
2. The sample length of this case is shown

Settings Section

3. To analyze data information and get results from cases.

⚠ **Notes**

⚠ **In this interface, the user can use the buttons**  **to change the print mode.**

⚠ **In this interface, the user can use the button**  **to print.**

⚠ **If a lead-off occurs during the sampling process, the waveform reviewed with the printed waveform will be marked with "*".**

⚠ **If lead overload occurs during the sampling process, the waveform reviewed with the printed waveform will be marked with a "+".**

7.5 Date and Time Setting

In the north interface, click 

to enter the following interface to set the date and time.

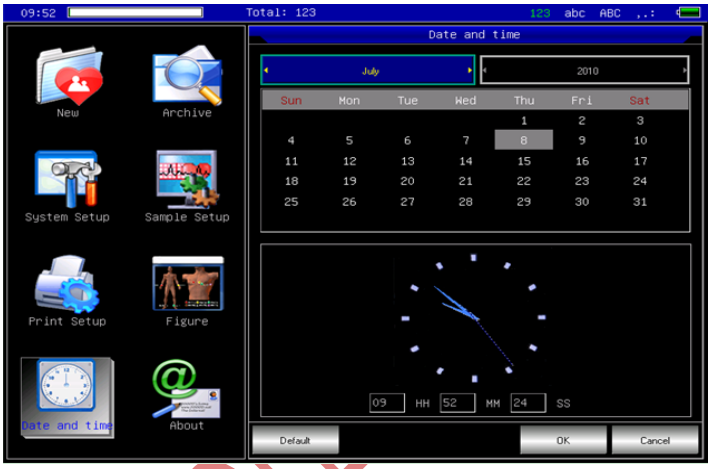


Figure 7-10

In this view, the user can select the  and buttons  to scroll through all items, and use the  and buttons  to customize the content of the selection. It can also be changed via the touch screen function, which is convenient and fast.

7.6 System settings

On the main interface, click 

to enter the system settings interface. The optional contents of each setting item and their description are shown in the following table:

Items	Choice	Description
Back light	[30 Seconds] / [1 Minute] / [2 Minutes] / [5 Minutes] / [10 Minutes] / [Always On]	If there is no operation after the set time, the backlight of the display will turn off. If set to “Always On”, the backlight is always on.
Light-degree	[10%degree] / [20%degree] / [30%degree] / [40%degree] / [50%degree] / [60%degree] / [70%degree] / [80%degree] / [90 %degree] / [100%degree]	After adjusting the light level, the screen will display different backlight strengths
Auto Off	[None] / [1 Minute] / [3 Minutes] / [5 Minutes] / [10 Minutes] / [15 Minutes] / [30 Minutes] / [60 Minutes]	If there is no operation after the set time, the system will automatically shut down If set to "None", the system will always power on
Low power	[None]/[Only Once] / [Always]	This determines which alarm method the Device uses in low power.
Language	[English] / [Chinese], etc	To set the system default language
Hospital	0-64 characters	to fill in the name of the hospital on the report
Heartbeat Sound	ON/OFF	to enable and disable the heartbeat sound
KB Sound	ON/OFF	KB sound on/off If selected, the button will make a sound when pressed, otherwise there will be no sound.

Demo Mode	ON/OFF		If selected, the system will run in Demo mode; otherwise, the system will run in sampling mode.
Sync setup	Sync Mode	[USB] / [Wi-Fi]	set sync mode
	Sync Host	----------	synchronize the IP address of the host
	Sync Port	6000 by default	set sync serial port
	MAC Address	----------	updated automatically after connecting
Default	all above settings will be returned to default after clicking this button		

7.7 Sampling Settings

On the main interface, click to enter the sampling settings. The optional contents of each setting item and description are shown in the following table:

Items	Choice	Description
AC filters	50Hz/60Hz	Set AC filter frequency
EMG filters	25Hz/30Hz/35Hz/ 40Hz/45Hz	Set EMG filter frequency
DFT filters	0.05Hz/0.5Hz/1Hz/ 0.15Hz/0.25Hz/0.32Hz	Set DFT filter frequency
LPF Filters	75Hz/100Hz/150Hz	Set LPF filter frequency
Show Style	[1 lead] / [3 leads] / [6 leads] / [12 leads]	Set ECG display method

Lead Order	[Routine Lead] / [Cabrera Lead]	Setting the order of leads
Show Gain	[2.5mm/mV] / [5mm/mV] / [10mm/mV] / [20mm/mV] / [40mm/mV] / [10/5mm/mV] / [20/10mm/mV] / 1.25 mm/mV	Set the displayed ECG gain
Show Speed	[5mm/s] / [6.25mm/s] / [10mm/s] / [12.5mm/s] / [25mm/s] / [50mm/s]	Set the displayed ECG speed
Background Grid	[Show] / [Not Show]	Set the background grid usage or not
Premature	0~100	To turn the heartbeat sound on or off
Pause for a moment	1200~3000	The system will use the input value as a standard to judge premature beats
Tachycardia	0~250	The system will use the input value as a standard for assessing tachycardia.
Bradycardia	0~99	The system will use the input value as the standard for assessing bradycardia.
Default	all above settings will be returned to default after clicking this button	

7.8 Print Settings

On the main interface, click 

to enter print settings. The optional contents of each setting item and description are shown in the following table:

Items	Choice	Description
Print Mode	[Auto 12x1] / [Auto 6x2+1] / [Auto 6x2+1_H] / [Auto 6x2] / [Auto 6x2_H] / [Auto 3x4+1] / [Auto 3x4+2] / [Auto 1x12] / [Rhythm 12] / [Rhythm 10] / [Rhythm 8] / [Rhythm 6]	The system takes the selected option as the default print mode
Lead Gain	[Smart] / [Current]	The selected option will be used as the print gain mode. "Smart" means the system will adjust the gain automatically to match the paper height; "Current" means it will use screen waveform gain just like printing.
Auto Strip	[2.5 sec] / [3 sec] / [4 sec] / [5 sec] / [6 sec] / [8 sec] / [10 sec] / [15 sec] / [20 sec] / [25 sec]	The system takes the selected option as the print time length of each strip.
Rhythm Strip	[10 sec] / [15 sec] / [20 sec] / [25 sec] / [30 sec]	When "Print Mode" is set to "Rhythm 12" "Rhythm 10" "Rhythm 8" or "Rhythm 6", the system takes the selected option as the print time length of each waveform

Average QRS	[3x4 + Mark] / [3x4] / [Not Print]	When "Print Mode" is set to "Auto" or "Rhythm", the system uses the selected format to print the average QRS waveform
Auto-Diagnosis	[All] / [Only data] / [Only conclution] / [Not Print]	The diagnosis contains two-part data and conclusions, which the user can select as a request.
Period	[Off] / [per 1 min] / [per 2 min] / [per 3 min] / [per 5 min] / [per 20 min] / [per 30 min] / [per 60 min]	During the ECG acquisition process, the system will automatically activate the printing operation according to the selected time interval. When printing mode is manual mode, printing will output "Auto 12x1" format, otherwise it will display according to current setting mode
Print Device	[Inside] / [Outside A4]	choose to print the ecg waveform with thermal printing system or USB external printer
Print Depth	[1] / [2] / [3] / [4]	adjust the wave depth according to need
Timing Markers	ON/OFF	set the appearance of the timestamp on the printed paper or not
Arrhythmia	ON/OFF	enable or disable arrhythmia analyzer

Note 1: Automatic strip setting, rhythm strip, average QRS, auto diagnosis, and periodic print are only optional in auto mode and rhythm mode.

Note 2: If the length of the printing time is less than 8 seconds, the sampling and analysis time is 8 seconds; if the length of the printing time is

equal to or greater than 8 seconds, the sampling and analysis time remains the same as the printing time.

On the print setting interface, click “Adv-opr” to enter the advanced setting interface. The optional contents of each setting item and description are shown in the following table:

Items	Choice	Description
Auto-Print	ON/OFF	set to open auto print or not
Data type	[Begin Print] / [After Print]	set to print the data before clicking the PRINT button, or after clicking
Rhythm 1	[I] / [II] / [III] / [aVR] / [aVL] / [aVF] / [V1] / [V2] / [V3] / [V4] / [V5] / [V6]	set the rhythm lead used to print under rhythm mode
Rhythm 2	[I] / [II] / [III] / [aVR] / [aVL] / [aVF] / [V1] / [V2] / [V3] / [V4] / [V5] / [V6]	set the "Auto 3x4+2" mode used for printing under rhythm mode
Conclusion title	[Conclusion] by default	set the printed conclusion title
Physician	[Physician] / [Specialist]	set doctor signature on printed report

7.9 Lead Laying

In the main interface, click 

to view the lead placement scheme diagram, European standard is shown below:

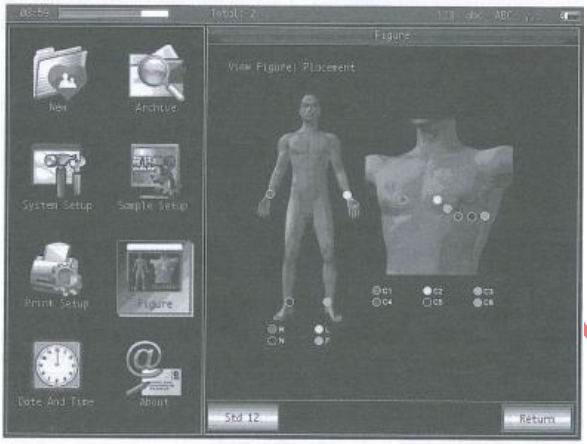


Figure 7-11

American standards are shown below:

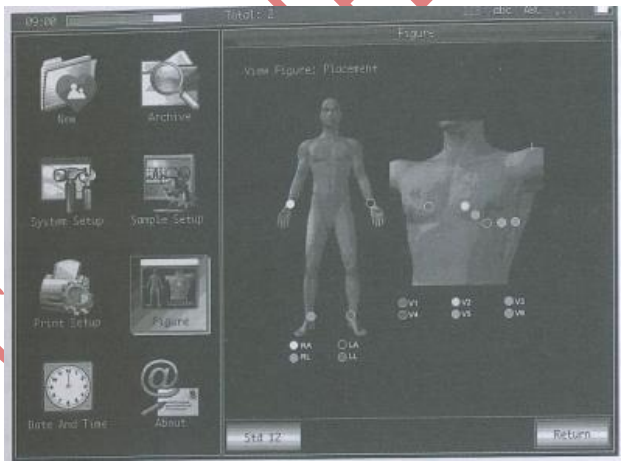


Figure 7-12

Click “Std 12” to change the schematic diagram of “Std 12” and “Add 6” lead placement.

Click "Return" to exit.

7.4.3 About

In the main interface, click  to view information about Devices, which includes content:

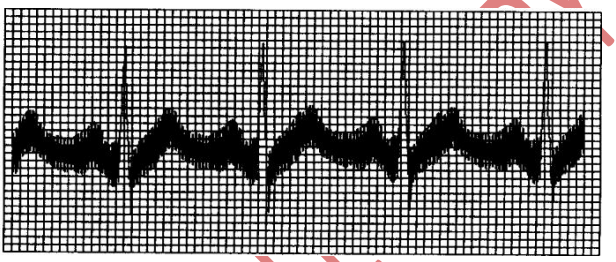
1. App Version: current Software version number
2. Firm Info: click to view Device firmware information
3. Return: click to exit interface

Chapter 8 Troubleshooting

8.1 Auto Power Off

- The battery is running low, which causes the overdischarge protection circuit to act.
- The AC power supply voltage is too high, which causes the action of the overvoltage protection circuit.

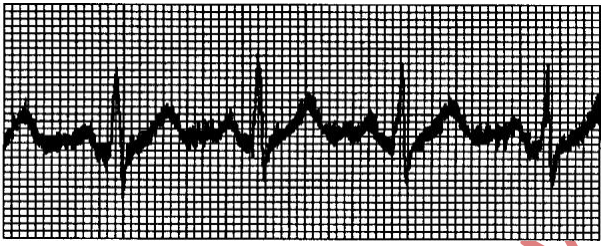
8.2 AC interface



- Is the Device reliably grounded?
- Are the electrodes or lead wires properly connected?
- Are the electrodes and skin stained with sufficient conductive paste?
- Are metal beds reliably grounded?
- Did the patient touch the walls or metal parts of the bed?
- Does the patient touch other people?
- Are there high-power electrical equipment working nearby? Such as X-ray machine or Ultrasonic Device, etc.

⚠ **Note: If the interference cannot be eliminated after performing the above actions, use an AC filter.**

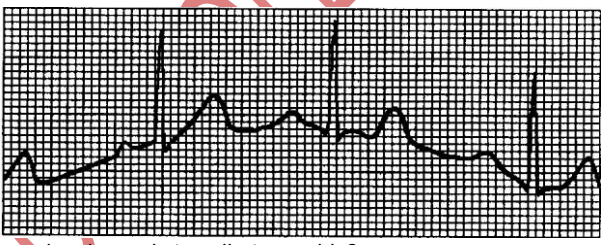
8.3 EMG interface



- Is the room comfortable?
- Is the patient nervous?
- Is the bedroom cramped?
- Did the patient speak during recording?
- Are the leg electrodes too tight?

⚠ **Note: If the noise cannot be removed after performing the above actions, use an EMG filter. The current recorded ECG waveform will be slightly attenuated**

8.4 Basic Shift



- Is the electrode installation stable?
- Is the lead wire or electrode connection reliable?
- Are the electrodes and patient's skin cleaned and smeared with sufficient conductive paste?
- Is it caused by the patient's movement or breathing?
- Are the electrodes or wires in a bad connection?

⚠ **Note: If the annoyance cannot be resolved after taking the above actions, use a basic filter.**

8.5 Troubleshooting List

Phenomenon	Cause of failure	Solution
The interference is too big, the waveform is irregular	1. The ground wire is not connected reliably. 2. Lead wires are not connected reliably. 3. There is an AC problem. 4. The patient is restless and cannot stay still.	1. Check the power cord and lead wires. 2. Let the patient prepare for the measurement.
Baseline	1. Big AC disturbance. 2. The patient is nervous, and the EMG disturbance is major.	1. Improve the environment. 2. If the bed is made of steel, replace it. 3. The power cable and lead are misaligned or too close to each other.
Not the usual waveform, big up and down, straight to the picture	1. Poor electrode conductivity. 2. Low battery. 3. Poor connection between the electrodes and the patient's skin. 4. Loose connection between main cable and Device plug. 5. Poor connection between	1. Use high quality alcohol. 2. Clean the electrode slices and the skin under the electrodes with alcohol. 3. Charging.

	electrodes and lead wires.	
Basic draft	1. low power. 2. Patient movement.	1. Charging. 2. Keep patient
Unclear waveform	1. Low battery. 2. The surface of the printer head is dirty. 3. Thermal paper problem.	1. Charging. 2. Turn off the power, clean the printer head with alcohol, dry it. 3. Replace thermal printing paper with specified

Chapter 9 Maintenance

9.1 Battery

9.1.1 This device is designed with a rechargeable and maintenance-free lithium battery, it is also equipped with a perfect automatic charging monitor system. When the Device is connected to AC power supply, the battery will be charged automatically. The battery status will be displayed on the right edge of the LCD screen when it is on, as shown in Table 9-1. Once completely discharged, the battery needs 5 hours to charge to 90%, and 5.5 hours to charge to full capacity.

Table 9-1 Battery status display

No.	icon	Description
a		Status unknown, usually displayed when the instrument is turned on in 1 minute
b		Using AC power
c		Using battery, and full power
d		Using battery, volume: 3/4
e		Using battery, volume: 1/2
f		Using battery, volume: 1/4
g		Using battery, but lower power, recommend recharging the battery or using AC AC power supply

Note: When charging the battery, the displayed battery level status will switch between f icon to c. icon

9.1.2 The device can print for 3 hours or work more than 10 hours in standby mode when the battery is fully charged. When the Device is

powered by battery, a battery icon will be displayed on the LCD screen, showing the battery capacity in 5 modes. When the battery capacity is too low for the operation of the Device, the Device will turn off automatically to avoid permanent damage to the battery.

Note: The above data was obtained by printing the demo waveform under a test environment of 25°C temperature, 25mm/s speed, and 10mm/mV gain. In actual use, the operating time may be shortened due to the operating conditions and environment

9.1.3 The battery should be recharged timely after it is completely discharged. If it is not used for a long time, the battery must be recharged every 3 months, which can extend the life of the battery.

9.1.4 When the battery is not rechargeable or works no more than 10 minutes after being fully charged, please replace the battery.

⚠ Notes:

- **Do not attempt to disassemble a sealed battery without permission. Battery replacement must be carried out by professional maintenance personnel authorized by our company, and the same model of rechargeable battery provided by our company must be used.**
- **Do not touch the positive and negative terminals of the battery directly with the wires, otherwise there is a fire hazard.**
- **Do not use the battery near sources of ignition or in an environment where the temperature exceeds 60°C. Do not heat the battery or throw it into fire, water and avoid splashing water.**
- **Do not puncture, hammer or hit the battery or destroy it in any other way, otherwise it will cause the battery to overheat, smoke, deform or a hazard of fire.**
- **Keep it away from the battery when it leaks or emits an unpleasant odor. If battery electrolyte leaks onto skin or clothing, wash it off immediately with water. If electrolytes accidentally get into your eyes, do not rub your eyes, wash them immediately with water and see a doctor.**
- **If the battery reaches its useful life, or the battery smells, changes shape, changes color, or is damaged, please stop using the battery and dispose of it in accordance with local regulations.**

9.2 Recording Paper

To ensure the quality of the ECG waveform, use high-speed thermal recording paper supplied or specified by the company. If you use unspecified recording paper, the recorded ECG waveform may be blurred, faded, and the paper feed may not be smooth. This can even increase Device wear and shorten the life of critical parts such as thermal print heads. For information on how to purchase the tape, please contact your dealer or company. Please be careful!

9.2.1 When using recording paper, it is absolutely not allowed to use recording paper with a waxy or grayish/black surface. Otherwise, the wax will stick to the printhead heating parts, resulting in abnormal jobs or damage to the printheads.

9.2.2 High temperature, humidity and sunlight can cause the recording paper to change color. Please store the recording paper in a dry and cool place.

9.2.3 Please do not place the recording paper under the fluorescent light for a long time, otherwise it will affect the recording effect.

9.2.4 Please do not mix the recording paper with PVC plastic, otherwise the color of the recording paper will change.

9.2.5 Please use the tape with the specified dimensions. Recording paper that does not meet the requirements may damage the thermal printhead or silicone rubber rollers.

9.3 Care after use

9.3.1 Press the button 

to turn off the Device.

9.3.2 Unplug the power cable and lead cable. Hold the plug head to remove it, and do not pull the cord directly.

9.3.3 Clean the Device and accessories, cover them from dust.

9.3.4 Store the Device in a cool and dry place, avoid strong vibrations when moving.

9.3.5 When cleaning the Device, do not immerse it in the cleaner. The power supply must be disconnected before cleaning. Use neutral detergent for cleaning. Do not use detergents or disinfectants that contain alcohol.

9.4 Leads and electrodes

9.4.1 The main cable connectivity can be detected by a multimeter. Check that each wire of the main cable is in good contact according to the following table. The resistance of each wire from the electrode plug to the corresponding pin in the main cable plug should be less than 10, The integrity of the lead wire should be checked regularly. Any damage to the lead wire will cause a false waveform of the corresponding wire or all of the wires on the ECG. The lead wires can be cleaned with a neutral solvent. Do not use detergents or disinfectants that contain alcohol (Please do not immerse the lead in liquid for cleaning).

Note: The resistance of the lead cable with defibrillation resistant protection function is about 10K.

Table 9-2 Lead wire markings and pin position wires

Tag	L (LA)	R (RA)	C1 (V1)	C2 (V2)	C3 (V3)	C4 (V4)	C5 (V5)	C6 (V6)	F (LL)	N (RL)
Pin position	10	9	12	1	2	3	4	5	11	14

9.4.2 Bending or knotting will shorten lead cable life. When using it, please straighten the lead wire first.

9.4.3 Electrodes must be stored properly. After prolonged use, the surface of the electrode may be oxidized and discolored due to corrosion and other factors, which may affect signal gain. In this case, the electrode must be replaced.

9.5 Silicone rubber roller

The silicone rubber roller must be smooth and free from smudges, otherwise it will affect the ECG recording effect. To remove stains on the rollers, use a clean soft cloth dampened with a small amount of alcohol to wipe them along the longitudinal direction, and roll the rollers in the direction of paper delivery while wiping them clean.

9.6 Cleaning the thermal thermal print leads

Dirt and dust on the surface of the TPH can affect the clarity of the waveform. To clean the surface of the printhead, open the paper compartment cover after turning off the Device, use a clean, soft cloth

moistened with alcohol to gently wipe the surface. For residual stains on the print head, moisten it with a small amount of alcohol first, then wipe with a soft cloth. Never use a hard object to scratch the surface, otherwise the printhead will be damaged. Wait for the alcohol to evaporate, then close the paper compartment cover. The printhead should be cleaned at least once a month during normal use.

9.7 Fuse Replacement

Use cross screwdriver to remove the fuse holder in the direction of the arrow (counterclockwise), and replace the damaged fuse with a master fuse supplied or approved by our company. Screw the fuse holder in the opposite direction to tighten. The switching mode is shown in Figure 9-1:

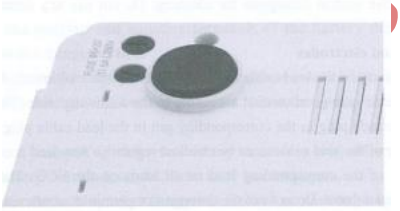


Figure 9-1

⚠ **Notes:**

⚠ **If the fuse blows again after replacing the fuse with the same specifications, The device may have other problems, please disconnect the power supply and contact the after-sales service of our company or the designated service center.**

⚠ **Push the fuse holder down and turn it counterclockwise as shown in Figure 9-1. After removing the faulty fuse and replacing a new one, press down on the fuse holder and turn it clockwise.**

9.8 Product waste disposal

Disposal of packaging materials, used batteries and expired Devices must comply with local laws and regulations, and users should treat used products and materials properly in accordance with laws and regulations, and try to support classification and recycling work.

9.9 Other

9.8.1 Do not open the cover of the Device to avoid electric shock hazard.

9.8.2 The Apparatus-related circuit schematics and lists of critical components are available only to authorized service stations or maintenance personnel, who are responsible for the maintenance of the Equipment.

9.8.3 The device belongs to the measuring instrument. The user must send the Device to the designated national inspection agency for inspection in accordance with the requirements of the national metrological verification procedure. Devices should be inspected at least once a year, and all accessories should be inspected and maintained regularly (at least every six months).

Chapter 10 Packing List and Accessories

10.1 Companion accessories

When the Device is shipped from the factory, the intact packaging must contain the following contents, as shown in Table 10-1:

Table 10-1 List of packaging and accessories

Name	Quantity
Electrocardiograph	1 piece
Chest electrode (suction cup/ slice electrode)	1 set (6pcs)
Leg electrode (leg clip)	1 set (4pcs)
ECG lead cable	1 piece
Potential equalization wire	1 piece
power cord	1 piece
User guide	2 pieces
Recording paper	3 pieces

10.2 Notes

10.2.1 Follow the instructions on the package when opening the package.

10.2.2 After unpacking, please check the accessories and accompanying documents according to the packing list, then start inspecting the Device.

10.2.3 If the contents of the package do not meet the requirements or the Device does not function properly, please contact our company immediately.

10.2.4 Please use the accessories provided by our company, otherwise the performance and safety of the Device may be affected. If the accessories provided by other companies need to be used, please consult the after-sales

service of our company first, or we will not be responsible for any damage caused.

10.2.5 Packages must be stored properly for future use in routine maintenance or repair of the Device.

Appendix I ECG Automated Measurement and Interpretation Guide

1. Foreword

The appendix describes the functions of automatic ECG measurement and automatic interpretation. it describes specific implementation methods, algorithms and formulas associated with these two functions, as well as content output with automatic measurement and automatic interpretation.

Conforms to the requirements of IEC60601-2-51:2003 Medical electrical equipment - part 2-51: Specific requirements for safety, including essential performance, recording and analysis of single-channel and multi-channel electrocardiographs, clause 50 accuracy of operating data, appendix providing a description of the verification process and results performance for automatic measurement and automatic interpretation.

2. Automatic measurement parameters and automatic interpretation items

Output measurement parameters, interpretation items and others that require explanation are as follows:

2.1 Measurement parameters

No.	Parameter	Unit
1	HR	bpm
2	PR interval	ms
3	duration P	ms
4	QRS duration	ms
5	duration T	ms
6	QT/QTc	ms
7	Electrical axis P/QRS/T	deg
8	R(V5)/S(V1)	mV
9	R(V5)+S(V1)	mV

2.2 Interpretation Items

no.	items
1	No abnormal
2	Sinus Bradycardia Mode
3	Tachycardia Sinus Mode
4	left atrial hypertrophy
5	Right atrial hypertrophy
6	Dual atrial hypertrophy
7	low voltage QRS
8	normal cardiac electrical axis
9	left axis deviation
10	right axis deviation
11	Completeness right bundle branch block
12	Completeness left bundle branch block
13	No Completeness right bundle branch block
14	No Completeness left bundle branch block
15	V1 displays RSR type'
16	left anterior fascicular block
17	left fascicular block
18	left ventricular hypertrophy
19	right ventricular hypertrophy
20	atrioventricular block I
21	Early anteroseptal MI
22	possible MI. acute anterior anteroseptal
23	Old anteroseptal MI
24	Early anterior MI
25	possible acute anterior MI

26	Old anterior MI
27	Early extensive anterior MI
28	possible acute extensive anterior MI
29	Long-standing extensive anterior MI
30	Early apical MI
31	Acute apical MI
32	Old apical MI
33	Early anterolateral MI
34	possibility of accurate anterolateral MI
35	Old anterolateral MI
36	Initial high lateral MI
37	high probability of acute lateral MI
38	Old high lateral MI
39	Early inferior MI
40	possible acute inferior MI
41	Old inferior MI
42	Early inferolateral MI
43	possible acute inferolateral MI
44	Old inferolateral MI
45	ST depression, mild anteroseptal myocardial ischemia
46	ST depression, mild anterior myocardial ischemia
47	ST depression, mild anterior extensive myocardial ischemia
48	ST depression, mild apical myocardial ischemia
49	ST depression, mild anterolateral myocardial ischemia
50	ST depression, mild high lateral myocardial ischemia
51	ST depression, mild inferior myocardial ischemia
52	ST depression, mild inferolateral myocardial ischemia
53	ST depression, anteroseptal myocardial ischemia
54	ST depression, anterior myocardial ischemia

55	ST depression, anterior extensive myocardial ischemia
56	ST depression, apical myocardial ischemia
57	ST depression, anterolateral myocardial ischemia
58	ST depression, high lateral myocardial ischemia
59	ST depression, inferior myocardial ischemia
60	ST depression, inferolateral myocardial ischemia

2.3 Intended use

The purpose of using the automatic measurement and interpretation function is shown below:

Application and diagnosis	In order to detect abnormal heart of the human body, check items refer to the description above
Population	teenagers and adults, age range: 12-87
applied site	hospital
accuracy	The accuracy of this function is reflected by the balance performance of sensitivity and specificity
etc	This function does not generate any alarm while using, so it must be operated by a trained professional or personal.

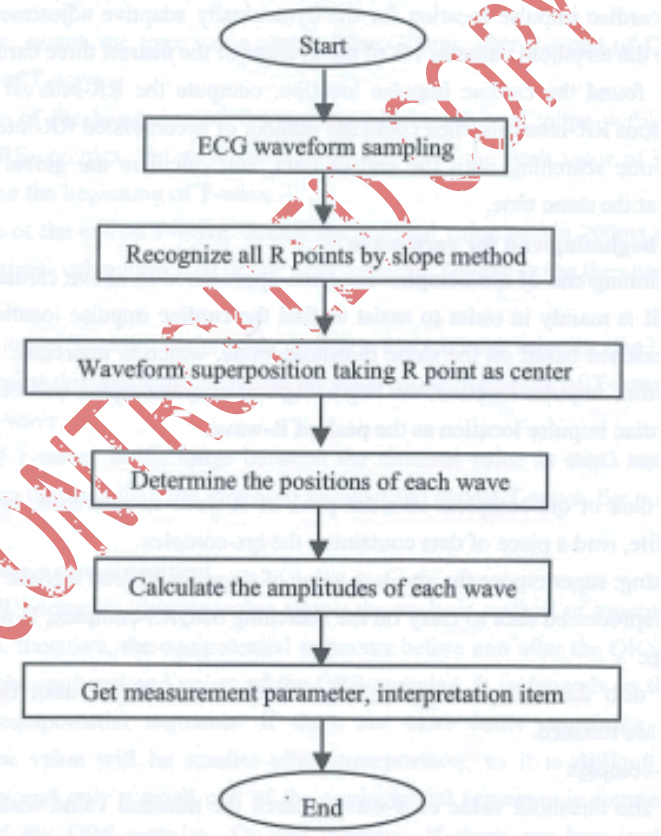
3. Algorithm description

This section describes the scoring algorithms, formulas, and conditions for interpretation items related to the ECG auto-measurement and auto-interpretation functions.

The 12-lead synchronized ECG waveform passes through the filters (AC, EMG, DFT (if available, and open)) into the automatic measurement and interpretation module.

The automatic measurement and automatic interpretation module mainly includes the process of locating the cardiac impulse, finding the start/end for each wave, its amplitude, calculation, parameter calculation, and interpretation assessment based on known parameters.

The workflow is shown as below:



3.1 Find the location of the cardiac impulse

1) Pre-processing of data, getting trend of absolute value of slope for each lead; then overlays each absolute value, obtaining a superimposed graph of the absolute value of the slope.
2) Superimposed graph smoothing filter 80ms width average, get DDD analytics data source.
3) Find the location of the cardiac impulse, provide an initial threshold for searching, scan the data regularly in the DDD analytical data source, then compare it with the threshold value:
   When the value is greater than the threshold, it may be the start of the qrs-complex.
   If the distance from the previous qrs complex to the current location is less than 150ms then drop the location.
   Otherwise, take 1/4 of the threshold value for reference, find the start of the qrs complex within 100ms before the current location.
   When the value is less than the threshold value, it may be the end of the qrs-complex. take 1/4 of the threshold value as reference, find the end of qrs-complex.
   If the found qrs complexes are wide, these qrs complexes should be excluded. Otherwise, save the qrs-complex.
4) Search: after finding the qrs-complex, find the point of maximum value between the start point and end point on the original ECG data, mark that point as the location of the heart impulse.
5) Dynamic threshold adjustment: after finding the location of the heart impulse, use the value at the location of the heart impulse for dynamic adaptive adjustment of the threshold value. Determine the threshold value as 1/3 of the average of the three closest cardiac impulses.
6) After finding the location of the heart impulse, calculate the RR interval and accumulate it with the previous RR interval, then calculate the number of accumulated RR intervals.
7) Continue serching until the end of the data, and calculate the global mean for the RR intervals together.

3.2 Find the start/suffix of each wave

The start/end of the qrs complex has been approximated in the process of locating the cardiac impulses above, but mainly to help locate the cardiac impulses; In addition, locations are searched based on imprecise slope threshold values . Here, according to the location of the cardiac impulse found, the start/end of the QRS complex will be accurately searched. Name the location of the cardiac impulse as the peak of the R wave.

1. Read data

1) Read a single qrs-complex data: take the R-wave peak as a reference, search directly to the original ecg file, read a piece of data containing the qrs-complex.

2) Preprocessing: assigns the absolute slope value for the 12-lead signal.

3) Use the preprocessed data to perform a search for the QRS complex, P wave and T wave as follows.

4) Read the next qrs-complex data, repeat step 2 and step 3 until the qrs-complex analysis is complete.

2. Find the QRS complex

1) Calculate the S-wave threshold value: find the minimum value within 200 ms after the peak of the R-wave, take the same value as the minimum value plus 0.4, as the threshold value to find the end of the S-wave.

2) Find the start of the Q-wave: take 0.5 as the threshold value, look ahead starting from the R-wave, the point less than the threshold value, within 0ms-200ms before the peak of the R-wave, which is the start of the Q-wave.

3) Find the end of the S-wave: look for a retreat starting from the R-wave, a point that is less than the threshold value of the end of the S-wave, within 0ms-200ms after the peak of the R-wave, which is the end of the S-wave.

3. Find the P-wave

    1) P-wave crest: find the maximum value within 30ms-100ms before the start of the Q-wave, mark the point as a temporary P-wave crest.

2) Find the end of the P-wave: find the minimum value between the peaks of the P-wave, the minimum value plus 0.06 is the threshold value, use the threshold value to find the start of the P-wave.
3) If the found P wave is narrow, examine the P wave according to the following steps.
4) Change the search range from 30ms-100ms to 100ms-350ms in step 1, repeat steps 1-4.
5) If the P wave is found to be still narrow, it means that the P wave is absent.

4. Find the T-wave
   1) T-wave peak: find the maximum value within 30ms-300ms after the end of the QRS complex, save it as a T-wave peak.
   2) T wave start threshold value: look for the minimum value within 0 ms-100 ms after the end of the QRS complex, the minimum value plus 1/10 of the peak value of the T wave is the threshold for finding the start of the T-wave.
   3) T-wave end threshold value: find the minimum value within 200 ms after the T-wave peak value, the minimum value plus 1/10 of the T-wave peak value is the threshold for finding the T-wave tip.
   4) Find the start of the T wave: in the range between the minimal value in step 2 and the crest of the T wave, find a point that is less than the threshold value of the start of the T wave, that point is the start of the T-wave.
   5) Find the tip of the T wave: in the range between the minimal value in step 3 and the crest of the T wave, find a point that is smaller than the threshold value of the T wave tip, that point is the end of the T-wave.

5. Explanation of equipotential segments

   In the QRS complex search, this algorithm adopts the slope superposition analysis method for all leads, therefore, equipotential segments before and after the QRS complex are partially included in the pints of the start and end of the QRS complex. This depends on the number of leads that contain equipotential segments. If there are

more segments, the slope value will be smaller after superposition, making it difficult to satisfy the threshold condition, and only a small number of equipotential segments are calculated to the starting and ending points of the QRS complex. On the other hand, if there are fewer leads containing equipotential segments, most of the equipotential segments will count towards the start and end points of the QRS complex. However, equipotential segments before and after the QRS complex are partly included in the duration of the QRS complex.

3.3 Amplitude Measurement

After finding the position of each wave, such as the start and end points of the P wave, QRS complex and T wave, use the method to measure the P, Q, R, S, ST, and T waves in each lead.

1. P Gelombang wave

Calculate the average value from the data 20ms before the start point of the P wave, and use this average value as the basis for the P wave. Find the maximum value between the start and end points of the P wave, the difference between this maximum and base being the amplitude of the P wave.

2. Q/R/S Gelombang wave

Calculate the mean value of the data 10-30ms before the starting point of the QRS complex, and use this average value as the basis for the QRS complex. Find a boundary point that extends beyond the baseline from the start point of wave Q to the end point of wave S. Every two adjacent boundary points create a sub-wave. Determine what is the minimum recognizable subwave (see explanation below). If the minimum wave can be recognized, first identify its direction. If it is above the bottom of the QRS complex, it is an R wave, if below it is a Q or S wave. Find the extreme value of this wave, and the difference between the extreme value and the base value is the amplitude of the Q/R/S wave.

⚠ Note: if there is only one downward wave, its amplitude must be recorded in terms of the amplitude of the Q wave and the S wave, respectively.

3. ST segment

Take above the QRS complex baseline as the ST baseline. Calculate the difference between the baseline St and the points at 40ms and 60ms after the endpoint of the QRS complex, and calculate the mean value of the two differences, the mean value being the amplitude of the ST segment.

4. T Gelombang wave

Calculate the average value from the data 20-50ms after the end point of the T wave, and average that value with the QRS complex base value in 2, then use the result as the T wave base value. Find the maximum value between the start and end points of the T wave , the difference between the maximum value and the base value will be the amplitude of the T wave.

5. Minimum wave recognition

The minimum waveform that can be identified by an algorithm according to the requirements of IEC6060-1-25-51:2003: Medical Electronic Equipment – Part 2-51: Specific requirements for safety, including critical performance, recording and analysis of single channel and multichannel electrocardiograph, Appendix GG , Clause GG.5 Definition of wave, measurement of minimum wave. The wave that will meet these conditions is the minimum wave that will be recognized by the algorithm.

1) One section under consideration clearly shows two opposite slopes with at least one turning point between them;
2) One section considered deviates at least 30 V from the reference level for a duration of at least 6ms;
3) The minimum observable duration of the wave under consideration is 12ms and the amplitude is 30 V.

3.4 Calculation after determination of interval

The following parameters are determined in accordance with the requirements of IEC 60601-2-51:2003 Medical electrical equipment - part 2-51: Special requirements for safety, including essential performance, recording and analysis of single-channel and multi-channel electrocardiographs, Annex GG Definitions and rules for ELECTROCARDIOGRAM measurements.

No.	Parameter	Calculation
1	HR	60/RR [a]
2	PR-interval	Qs [b] – Ps [c]
3	P-duration	Pe [d] – Ps [c]
4	QRS-duration	Se [e] – Qs [b]
5	T-duration	Te [g] – Ts [f]
6	QT	Te [g] – Qs [b]
7	QTc	$\frac{QT}{\sqrt{RR^a}}$
8	P/QRS/T electric axis	Electric axis formula: $\frac{\arctan(2.0 \times (S_{III} + S_I), S_I \times \sqrt{3}) \times 180}{PI^h}$ P electric axis: S_{III} : voltage sum from the beginning point to the end point of P-wave on lead III S_I : voltage sum from the beginning point to the end point of P-wave on lead I QRS electric axis: S_{III} : voltage sum from the beginning point to the end point of QRS-complex on lead III S_I : voltage sum from the beginning point to the end point of QRS-complex on lead I T electric axis:

		S_{III} : voltage sum from the beginning point to the end point of T-wave on lead III S_{I} : voltage sum from the beginning point to the end point of T-wave on lead I
9	R(V5)	Height (voltage value) of R-wave on lead V5
10	S(V1)	Height (voltage value) of S-wave on lead V1

⚠ Notes:

a. RR: RR-interval
b. Qs: beginning of the Q-wave
c. PS: beginning of the P-wave
d. Pe: end of the P-wave
e. Se: end of the S-wave
f. Ts: beginning of the T-wave
g. Te: end of the T-wave
h. PI: 3.1415926

3.5 Interpretation assessment based on parameters

NO.	Items	Rules of interpretation
1	No abnormal	No any abnormal are detected
2	Bradycardia fashion sinus	Sine P-wave, PR-interval between 110ms-210ms, HR * /min, general *=50
3	Sinus mode Tachycardia	Sine P-wave, PR-interval between 110ms-210ms, HR */min, general *=100

4	Left atrial hypertrophy	P-wave of leads I, QQ, aVL shall meet the conditions: width increase of P-wave 110ms , or P-wave displays in double-peak type, value of peak to peak 40ms.
5	Right atrium hypertrophy	For lead I, II, aVF, amplitude of P-wave 0.25mV , or P-wave is sharp
6	Dual atrium hypertrophy	For lead I, II, aVF, amplitude of P-wave 0.25mV , and P-wave > 110ms
7	QRS low voltage	Voltage of I-aVF limb leads < 0.5mV, and voltage of V1-V6 chest leads < 0.8mV
8	Cardiac electric axis normal	QRS-axis between 30 to 90 degree
9	Left axis deviation	QRS-axis between -90 to -30 degree
10	Right axis deviation	QRS-axis between 120 to 180 degree
11	Completeness Right Bundle branch block	QRS-duration>120ms, R-wave of lead V1 or a VR is wide (width of R-wave>80ms)

12	Completeness Left Bundle branch block	QRS-duration>120ms, R-wave of lead V5 or V6 is wide
13	No Completeness Right Bundle branch block	QRS-duration<120ms, R-wave of lead V1 or a VR is wide (width of R-wave>80ms)
14	No Completeness Left Bundle branch block	QRS-duration<120ms, R-wave of lead V5 or V6 is wide (width of R-wave>80ms)
15	V1 shows RSR' type	QRS-complex of lead V1 is RSR' type
16	Left anterior fascicular block	QRS-duration<110ms, QRS-axis < -30 degree, lead I and lead aVL are qR type, and Q-wave duration <20ms, lead II, III, and aVF are rS type.
17	Left posterior fascicular block	QRS-duration<110ms, QRS-axis >90 degree, lead I and lead aVL are rS type, and Q-wave of lead II and III <20ms, lead II, III, and aVF are qR type.
18	Left ventricular hypertrophy	R amplitude of lead I >1.5mV, R amplitude of lead V5 > 2.5mV, R amplitude of lead aVL >1.2mV, R amplitude of lead aVF >2mV, R amplitude of lead V5 minus S amplitude of lead V1 >4mV (male) or 3.5mV (female)

19	Right ventricular hypertrophy	R amplitude of lead aVR>0.5mV, R amplitude of lead V1 >1mV, R amplitude of leadV1 minus S amplitude of lead V5 >1.2mV, R amplitude of lead V1 is larger than S amplitude, R amplitude of lead V5 is smaller than S amplitude.
20	I atrioventricular block	PQ interval >210ms
21	Early anteroseptal MI	Early myocardial infarction change of leads V1, V2, V3, no change of leads V4, V5.
22	Possible acute forepart anteroseptal MI	Acute myocardial infarction change of leads V1, V2, V3, no change of leads V4, V5.
23	Old anteroseptal MI	Old myocardial infarction change of leads V1, V2, V3, no change of leads V4, V5.
24	Early anterior MI	Early myocardial infarction change of leads V3, V4, V5, no change of leads V1, V2, V6.
25	Possible acute anterior MI	Acute myocardial infarction change of leads V3, V4, V5, no change of leads V1, V2, V6.

26	Old anterior MI	Old myocardial infarction change of leads V3, V4, V5, no change of leads V1, V2, V6.
27	Early extensive anterior MI	Early myocardial infarction change of leads V1, V2, V3, V4, V5.
28	Possible acute extensive anterior MI	Acute myocardial infarction change of leads V1, V2, V3, V4, V5.
29	Old extensive anterior MI	Old myocardial infarction change of leads V1, V2, V3, V4, V5.
30	Early apical MI	Early myocardial infarction change of leads V4, V5, no change of leads V1, V2, V3.
31	Possible acute apical MI	Acute myocardial infarction change of leads V4, V5, no change of leads V1, V2, V3.
32	Old apical MI	Old myocardial infarction change of leads V4, V5, no change of leads V1, V2, V3.
33	Early anterolateral MI	Early myocardial infarction change of leads I, aVL, V4, V5, V6.

34	Possible acute anterolateral MI	Acute myocardial infarction change of leads I, aVL, V4, V5, V6.
35	Old anterolateral MI	Old myocardial infarction change of leads I, aVL, V4, V5, V6.
36	Early high lateral MI	Early myocardial infarction change of leads I, aVL, no change of leads II, III, aVF, V4, V5, V6.
37	Possible acute high lateral MI	Acute myocardial infarction change of leads I, aVL, no change of leads II, III, aVF, V4, V5, V6.
38	Old high lateral MI	Old myocardial infarction change of leads I, aVL, no change of leads II, III, aVF, V4, V5, V6.
39	Early inferior MI	Early myocardial infarction change of leads II, III, aVF, no change of leads i, aVL.
40	Possible acute inferior MI	Acute myocardial infarction change of leads II, III, aVF, no change of leads i, aVL.

41	Old inferior MI	Old myocardial infarction change of leads II, III, aVF, no change of leads i, aVL.
42	Early inferolateral MI	Early myocardial infarction change of leads II, III, aVL, aVF.
43	Possible acute inferolateral MI	Acute myocardial infarction change of leads II, III, aVL, aVF.
44	Old inferolateral MI	Old myocardial infarction change of leads II, III, aVL, aVF.
45	ST depression, mild anteroseptal myocardial ischemia	Mild ST-segment depression of leads V1, V2, V3, and no change of leads V4, V5.
46	ST depression, mild anterior myocardial ischemia	Mild ST-segment depression of leads V3, V4, V5, and no change of leads V1, V6.
47	ST depression, mild extensive anterior myocardial ischemia	Mild ST-segment depression of leads V1, V2, V3, V4, V5.
48	ST depression, mild apical myocardial ischemia	Mild ST-segment depression of leads V4, V5, and no change of leads V1, V2, V3.
49	ST depression, mild anterolateral myocardial ischemia	Mild ST-segment depression of lead I, aVL, V4, V5, V6.

50	ST depression, mild high lateral myocardial ischemia	Mild ST-segment depression of lead I, aVL, and no change of leads II, III, aVF, V4, V5, V6.
51	ST depression, mild inferior myocardial ischemia	Mild ST-segment depression of leads II, III, aVF, and no change of leads I, aVL.
52	ST depression, mild inferolateral myocardial ischemia	Mild ST-segment depression of leads I, II, III, aVL, aVF.
53	ST depression, anteroseptal myocardial ischemia	Severe ST-segment depression of leads V1, V2, V3, and no change of leads V4, V5.
54	ST depression, anterior myocardial ischemia	Severe ST-segment depression of leads V3, V4, V5, and no change of leads V1, V6.
55	ST depression, extensive anterior myocardial ischemia	Severe ST-segment depression of leads V1, V2, V3, V4, V5.
56	ST depression, apical myocardial ischemia	Severe ST-segment depression of leads V4, V5, and no change of leads V1, V2, V3.
57	ST depression, anterolateral myocardial ischemia	Severe ST-segment depression of lead I, aVL, V4, V5, V6.
58	ST depression, high lateral myocardial ischemia	Severe ST-segment depression of lead I, aVL, and no change of leads II, III, aVF, V4, V5, V6.

59	ST depression, inferior myocardial ischemia	Severe ST-segment depression of leads II, III, aVF, and no change of leads I, aVL.
60	ST depression, inferolateral myocardial ischemia	Severe ST-segment depression of leads I, II, III, aVL, aVF.

⚠ Notes:

Early myocardial infarction: normal Q-wave, ST elevation or ST slope elevation

Acute myocardial infarction: abnormal Q-wave, ST elevation or ST slope elevation

Old myocardial infarction: abnormal Q-wave, no ST elevation.

Q-wave abnormalities:

For leads I, II, III, aVR, aVL, aVF, V3, V4, V5, V6, voltage of Q-wave <-0.3mV, or 4 times of negative wave of Q-wave> voltage of R-wave and R '-wave, and/or Q-duration>40ms.

For leads V1, V2, voltage of Q-wave <-0.08mV and Q-duration>10ms.

ST elevation:

For leads I, II, III, aVR, aVL, aVF, V4, V5, V6, the voltage of ST-segment at 60ms point >0.1mV, and for leads V1, V2, V3, the voltafe at 60ms point>0.3mV .

ST slope elevation:

Voltage of ST segment at 20ms point>= voltage of J point, voltage at 40ms point >= the one at 20ms, voltage at 60ms point >= the one at 40ms, with change of ST elevation.

4. Data sources and data pre-processing

4.1. Data source

According to the requirements of IEC 60601-2-51:2003 Medical electrical equipment - part 2-51: Specific requirements for safety, including essential performance, recording and analysis of single-channel and multi-channel electrocardiograms, CSE measurement databases, CSE diagnostic databases,

CTS calibration databases and adjusted data should be used to evaluate the automatic measurement function and automatic interpretation.

Verification	Databases	Database items
Automated measurement	CTS database	CAL05000 CAL10000 CAL15000 CAL20000 CAL20002 CAL20100 CAL20110 CAL2160 CAL20200 CAL20210 CAL20260 CAL20500 CAL30000 ANE20000 ANE20001 ANE20002
	CSE measurement database	MA_0001 ~ MA0125
Automated interpretation	CSE diagnostic database	D_0001 ~ D_1220
	Customized	000001 ~ 000549

4.2. Introduction to CTS

The CTS computerized ECG conformance testing project was launched in 1989 by the European Union. This project laid the foundation for a computerized ECG conformance testing service. At present, about 20 types of waveforms have been designed which are derived from test signals of infinite length, these signals are part of the CTS-EKG test database, and have been proven to be effective in a series of official tests. According to the requirements of IEC 60601-2-51:2003 Medical electrical equipment - part 2-51: Special requirements for safety, including essential performance, recording and analysis of single-channel and multi-channel electrocardiographs Clause 50.101.1, 13 data (CAL05000 CAL10000 CAL15000 CAL20000 CAL20002 CAL20100 CAL20110 CAL201160 CAL20200 CAL20210 CAL20260 CAL20500 CAL30000) is used for the automatic verification parameters for this test.

4.3. Introduction to CSE

The EU CSE (General Standard for Quantitative Electrocardiography) ECG database contains a 3-lead measurement database from collection1 and collection2, a 12-lead measurement database for collection3 and collection4, and a collection diagnostic database5. Wherein, the 12-lead measurement database contains 250 groups of interference data; The diagnostic database contains 1220 cases of short-term ECG recordings. The main development goal of using 12 leads or 15 leads was to evaluate the performance of an automated ECG analyzer. In addition to normal data, the database also includes clinically confirmed ECG of various cases, such as left ventricular hypertrophy, right ventricular hypertrophy, any part of myocardial infarction and ventricular hypertrophy accompanying myocardial infarction. The database has made a great contribution to the study of electrocardiology, namely, the CSE group published reports of recommended standards for general ECG measurements based on investigations and database studies, which have been widely recognized by the world.

CSE database diagnostic items:

Items	Number
Normal	382
Left ventricular hypertrophy	183
Right ventricular hypertrophy	55
Biventricular hypertrophy	53
Anterior myocardial infarction	170
Inferior myocardial infarction	273
Complex myocardial infarction	104
Synthetic accuracy	1220

4.4. Customized data

Description of data:

Customized data	Description
Total recording number	549
Race	Yellow race
Coverage of age, gender	Aged from 17 to 87, average age 57.23, standard deviation 21.32; 326 male, average age 55.54, standard deviation 19.81; 223 female, average age 59.70, standard deviation 22.63
Sampling data	12 lead ECG data (I, II, II, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6), sampling frequency of each channel: 1kHz, amplitude quantization: 2.4
Remark	The interpretation conclusion of customized data is determined by the physician diagnostic results of cardiac catheterization and ultrasound examination, and the ECG judgment result in physical examination, the details as below: 1) Normal ECG Determined by the diagnostic result that judged as normal in cardiac catheterization and ultrasonic examination, and the result

	that judged as normal in physical examination. 2) Atrial hypertrophy Determined by the diagnostic result of ultrasonic examination. 3) Myocardial infarction and myocardial ischemia Determined by physician diagnostic results of cardiac catheterization. 4) Tachycardia, bradycardia, low voltage, axis Determined by diagnostic result of ultrasonic examination. 5) Conduction block Determined by the physician diagnostic result of cardiac catheterization. The standard of normal population in the customized database: physical examination is normal, no heart disease or other diseases that may affect cardiac functions or shape.

4.5. Verification data coverage for automatic interpretation

Analyzing the contents of the CSE diagnostic database and the adjusted data, the overall condition and scope of the statistical sample is shown as follows:

	Total					Male					Female				
	Youngest	Oldest	Average	SD	Total	Youngest	Oldest	Average	SD	Total	Youngest	Oldest	Average	SD	Total
Total	12	87	34.87	13.34	1769	14	87	34.33	14.33	1157	12	80	35.89	13.48	612

SD: standard deviation

Unit: years

No.	Items	Total					Male					Female				
		Youngest	Oldest	Average	SD	Total	Youngest	Oldest	Average	SD	Total	Youngest	Oldest	Average	SD	Total
1	No abnormal	12	87	47.39	18.21	585	14	79	46.37	17.51	234	12	87	48.07	18.32	351
2	Sinus node Bradycardia	14	83	51.62	17.83	191	14	83	53.34	18.12	114	15	83	48.68	16.99	77
3	Sinus node Tachycardia	19	79	38.28	16.97	78	23	56	33.33	18.78	23	19	79	40.81	17.63	55
4	Left atrium Hypertrophy	17	81	49.53	13.37	51	17	72	45.78	13.45	31	21	81	55.33	13.02	20
5	Right atrium Hypertrophy	18	56	48.71	13.34	43	19	71	47.21	14.56	27	18	56	51.34	13.29	16
6	Dual atrium Hypertrophy	26	77	51.33	16.49	22	26	75	49.91	16.13	15	29	77	54.34	15.47	7
7	QRS low-voltage	33	67	52.44	13.83	5	32	32	32	0	1	33	67	52.55	15.99	4
8	Cardiac electric axis normal	12	87	48.97	19.86	733	12	85	46.52	18.98	304	14	87	50.71	19.26	429
9	Left axis deviation	27	73	49.48	13.71	108	28	73	48.73	14.27	84	27	71	49.66	13.09	81
10	Right axis deviation	26	77	52.36	14.68	107	26	72	51.85	13.11	56	27	77	53.36	14.59	51
11	Completeness Right Bundle branch block	46	78	56.97	11.33	28	46	75	55.86	10.89	15	50	78	58.25	11.28	13
12	Completeness Left Bundle branch block	44	79	56.99	10.83	32	44	73	55.72	10.21	18	52	79	58.62	9.34	14
13	No Completeness Right Bundle branch block	41	73	53.83	11.14	41	41	71	55.11	10.75	24	47	73	56.85	11.06	17
14	No Completeness Left Bundle branch block	43	71	55.76	10.38	47	43	69	54.36	10.23	31	48	71	58.47	10.67	16
15	WL shown RSR' type	37	73	56.81	15.77	13	37	74	56.16	15.46	10	40	75	58.98	17.69	3
16	Left anterior fascicular block	38	81	57.66	17.49	26	38	81	55.82	17.93	15	40	81	60.17	18.06	11
17	Left posterior fascicular block	42	78	58.78	16.88	18	43	70	55.16	17.93	13	41	77	60.02	17.69	8
18	Left ventricular hypertrophy	29	85	58.76	19.23	226	29	83	57.98	19.67	184	32	85	61.25	18.76	52
19	Right ventricular hypertrophy	27	84	59.31	19.54	108	27	79	58.89	20.04	71	31	84	60.65	19.33	37
20	Interventricular block	19	78	57.62	18.73	13	19	74	57.84	18.92	9	20	76	58.93	18.77	4
21	Early anteroseptal MI	48	83	63.48	10.24	18	48	80	61.39	10.29	7	59	83	68.36	12.84	3
22	Possible acute frontart anteroseptal MI	53	73	60.48	9.71	27	53	70	59.99	9.64	19	62	73	61.64	8.12	8
23	Old anteroseptal MI	55	82	65.37	9.17	26	55	80	64.78	10.08	20	58	82	67.34	8.68	6
24	Early anterior MI	47	76	61.26	10.41	73	47	71	60.32	9.62	53	55	76	63.24	9.77	24
25	Possible acute anterior MI	51	77	63.81	9.16	10	51	69	62.14	9.45	8	64	77	70.40	9.21	2
26	Old anterior MI	53	83	66.48	9.88	13	53	81	65.94	9.36	9	62	83	67.30	9.27	4
27	Early extensive anterior MI	52	75	60.35	11.74	24	52	72	59.88	11.32	17	58	75	61.49	12.36	7
28	Possible acute extensive anterior MI	55	79	63.81	12.34	16	55	75	61.38	10.63	11	58	79	67.33	11.21	6
29	Old extensive anterior MI	60	86	65.37	10.08	30	60	80	64.37	10.66	21	63	86	67.70	10.74	9
30	Early apical MI	39	71	60.36	12.47	15	39	69	60.18	12.76	10	47	71	60.72	11.28	5
31	Acute apical MI	45	77	62.58	11.37	21	45	74	62.69	12.03	16	50	77	62.23	12.46	5
32	Old apical MI	52	82	65.74	10.84	19	52	70	62.35	11.39	15	57	82	68.93	11.94	4
33	Early anterolateral MI	47	93	60.37	11.62	36	47	80	60.21	12.46	28	55	93	60.95	12.68	8
34	Possible acute anterolateral MI	55	80	65.77	10.68	9	55	75	62.18	11.62	7	58	80	69.34	13.08	2
35	Old anterolateral MI	56	82	64.82	10.73	14	56	76	64.05	11.62	10	68	82	66.75	10.47	4
36	Early high lateral MI	48	73	61.38	10.79	16	48	70	60.46	10.88	12	54	72	64.14	8.29	4

37	Possible acute high lateral MI	54	72	63.34	9.89	8	54	70	62.67	8.01	7	68	68	68.00	0	1
38	Old high lateral MI	55	77	65.17	11.44	23	55	74	64.89	18.12	17	58	77	68.23	9.94	6
39	Early inferior MI	46	74	61.31	12.55	31	46	70	61.02	11.81	22	50	74	62.02	11.75	9
40	Possible acute inferior MI	53	76	62.48	10.99	11	53	74	62.13	11.04	8	56	76	63.41	10.96	3
41	Old inferior MI	56	81	65.37	9.79	101	56	76	65.01	18.61	72	60	81	66.26	9.96	29
42	Early inferolateral MI	44	72	60.18	12.71	73	44	70	59.89	13.53	52	50	72	60.90	13.33	21
43	Possible acute inferolateral MI	50	78	63.47	10.77	29	50	75	62.49	11.62	20	53	78	65.65	11.78	9
44	Old inferolateral MI	56	83	66.56	9.83	28	56	80	65.41	9.98	19	60	83	68.99	8.24	9
45	ST depression, mild anteroseptal myocardial ischemia	45	74	62.34	12.77	7	45	70	62.47	11.99	3	50	74	62.02	16.94	2
46	ST depression, mild anterior myocardial ischemia	44	72	61.59	12.69	3	44	72	61.13	12.76	4	63	63	63.00	0	1
47	ST depression, mild extensive anterior myocardial ischemia	46	73	62.77	11.98	13	46	69	62.18	12.26	9	54	73	64.10	10.65	4
48	ST depression, mild apical myocardial ischemia	45	73	61.62	11.87	17	45	71	61.33	11.64	18	51	73	62.03	11.29	7
49	ST depression, mild anterolateral myocardial ischemia	44	74	60.97	12.65	25	44	72	60.07	12.39	15	58	74	62.32	12.84	10
50	ST depression, mild high lateral myocardial ischemia	46	81	64.36	12.31	21	46	76	63.94	11.82	16	53	81	65.70	12.74	5
51	ST depression, mild inferior myocardial ischemia	43	76	63.41	12.46	12	43	74	62.89	12.13	18	56	76	66.01	14.13	2
52	ST depression, mild inferolateral myocardial ischemia	39	72	62.78	12.38	20	39	69	62.11	12.12	13	44	72	63.97	13.37	7
53	ST depression, anteroseptal myocardial ischemia	49	78	65.61	11.62	4	49	78	65.24	14.81	3	63	67	67.00	0	1
54	ST depression, anterior myocardial ischemia	51	79	66.73	11.53	12	51	74	65.89	11.34	8	62	79	68.41	10.49	4
55	ST depression, extensive anterior myocardial ischemia	50	79	67.26	11.69	7	50	76	66.85	11.07	5	57	79	68.24	13.22	2
56	ST depression, apical myocardial ischemia	48	85	65.39	11.39	18	49	83	65.09	11.79	11	56	85	65.86	12.04	7
57	ST depression, anterolateral myocardial ischemia	52	83	66.93	10.97	13	53	83	66.42	12.32	7	52	81	67.53	11.69	6
58	ST depression, high lateral myocardial ischemia	53	84	65.74	10.88	16	54	84	65.16	12.36	9	53	82	66.48	11.47	7
59	ST depression, inferior myocardial ischemia	48	81	63.82	11.03	12	49	77	63.28	12.27	9	55	81	67.44	13.04	3
60	ST depression, inferolateral myocardial ischemia	49	82	66.04	11.14	6	49	79	65.49	16.88	4	52	82	67.14	21.02	2

⚠ Notes:

Cardiac abnormalities such as posterior myocardial ischemia, early posterior MI and prolonged posterior MI were not included in the database. These and other cardiac abnormalities not listed in the above sheet will not be considered as objects of assessment for verification of the accuracy of automatic interpretation.

4.6. Data Pre-processing

4.6.1. CTS pre-processing

16 cases (CAL05000 CAL10000 CAL15000 CAL20000 CAL20002 CAL20100 CAL201110 CAL2160 CAL20200 CAL20210 CAL20260 CAL20500 CAL30000 ANE20000 ANE20001 ANE20002) of CTS-ECG must be processed for voltage conversion and frequency conversion for resampling as the applicable

format in the system. Then the case will be imported to Devices. After that, automatic verification of measurement parameters will be carried out.

4.6.2. CSE pre-processing

Cases (MA_0001 ~ MA0125, D_0001 ~ D_1220) of the CSE should be processed for voltage conversion and frequency conversion for re-sampling as the applicable format in the system. Then the case will be imported to decive. After that, the MA_0001 ~ MA0125 box should be used for the following automatic verification of measurement parameters, and the D_0001 ~ D_1220 box should be used for the following automatic interpretation verification.

4.6.3. Customized data pre-processing

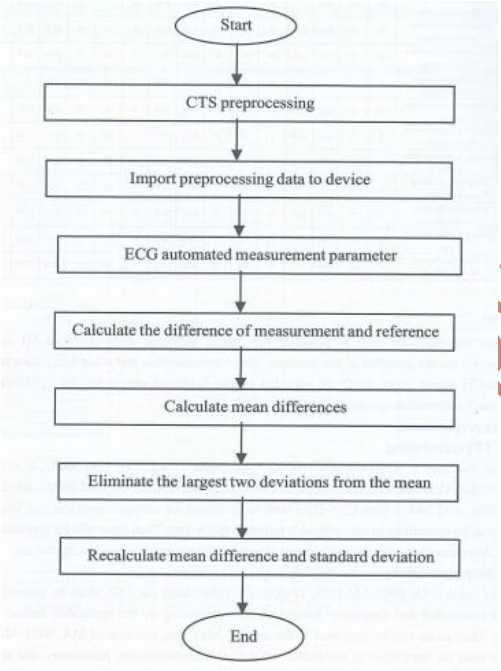
Customized initial case files should be processed for voltage conversion and frequency conversion for re-sampling as the applicable formats in the system. Then the case will be imported to Devices. After that, automatic interpretation verification will be performed.

5. Verification process and results

5.1 Verify measurement function

5.1.1 Verification and Process for CTS measurement database

Cases (CAL05000 CAL10000 CAL15000 CAL20000 CAL20002 CAL20100 CAL201110 CAL2160 CAL20200 CAL20210 CAL20260 CAL20500 CAL30000 ANE20000 ANE20001 ANE20002) imported into the Device must be used to verify the automatic measurement parameters.



5.1.2 Verification and Process for CSE measurement database

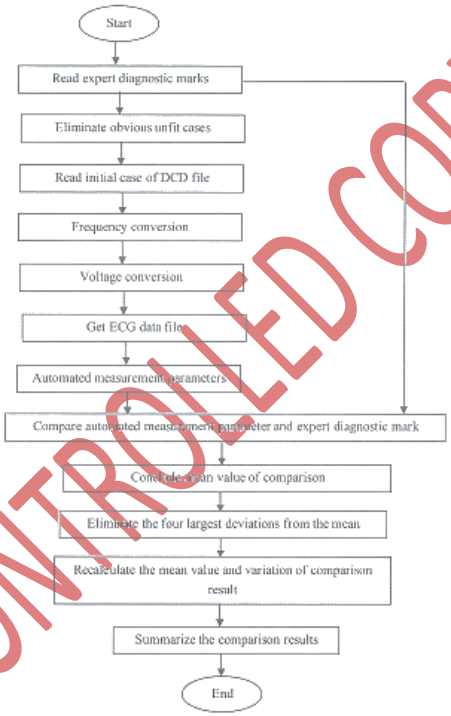
Import converted case files to Device , add appropriate database records, then waveforms for all case files can be reviewed in Device , therefore automatic measurement parameters can be obtained.

Eliminate existing real error cases for diagnostic parameters (incorrect P wave location) from the CSE database.

Make comparisons between the analytical parameters of the ECG (beginning/end of P wave, QRS complex and T wave) and diagnostic parameters (beginning/end of P wave, QRS complex and T wave) provided by the CSE database. Draw two groups of waveforms and mark the start/end location of the P wave, QRS complex and T wave as appropriate for each case. The figure provides a visualized comparison, so that the mean and standard deviation of the differences can be calculated. According to the requirements of IEC60601-2-51:2003 Medical electrical equipment - Part 2-51: Special

requirements for safety, including essential performance, recording and analysis of single-channel and multi-channel electrocardiographs, the four largest deviations from the mean must be eliminated before recalculation of the mean and standard deviation of the difference.

CSE measurement database verification process flow chart.



5.1.3 Verification result

5.1.3.1 Amplitude measurement accuracy

Calibration and analytical ECGs shall be used to measure the amplitude value, the summary as follows:

Amplitude	Mean difference (uV)	Standard deviation (uV)
P-wave	-1.70	5.72
Q-wave	7.51	18.07
R-wave	-18.05	21.70
S-wave	7.77	18.58
ST-segment	0.15	4.24
T-wave	-5.81	8.03

⚠ Note: In amplitude measurement, for large amplitude ECG, such as CAL30000, it is necessary to adjust up to 0.5 times the gain before testing.

5.1.3.2 Absolute interval accuracy and wave duration measurement

Calibration and analytical ECG should be used to measure the global interval and duration of waves (including Q waves, R waves, S waves), a summary of which is as follows:

Interval&Duration	Mean difference (ms)	Standard deviation (ms)
P-duration	-5.70	1.88
PQ-interval	-2.58	1.94
QRS-duration	-0.23	3.26
QT-interval	-6.70	4.37

5.1.3.3 Interval measurement accuracy on biological ECG

The CSE database should be used to evaluate the accuracy of interval measurements on the biological ECG, a summary of which is as follows:

Interval&Duration	Mean difference (ms)	Standard deviation (ms)
P-duration	0.99	13.46
PR-interval	3.65	9.68
QRS-duration	-1.69	6.11
QT-interval	-2.32	20.69

5.1.3.4 Measurement stability against NOISE

The tests were carried out according to the MA series data (008, 011, 013, 014, 015, 021, 026, 027, 042, 061) in the CSE database.

Global measurement parameters	Type of added NOISE	Disclosed differences	
		Mean (ms)	Standard deviation (ms)
P-duration	High frequency	-5.65	12.33
P-duration	Line frequency	-0.25.	12.71
P-duration	Base-line	-4.90	33.15
QRS-duration	High frequency	-0.95	5.13
QRS-duration	Line frequency	1.35	4.71
QRS-duration	Base-line	-1.55	7.68
QT-interval	High frequency	-14.55	6.51
QT-interval	Line frequency	-8.55	20.73
QT-interval	Base-line	36.20	64.47

The biological ECG is entered into the Device in the form of a digital signal, then the measurement value can be obtained by calculation.

Condition test:

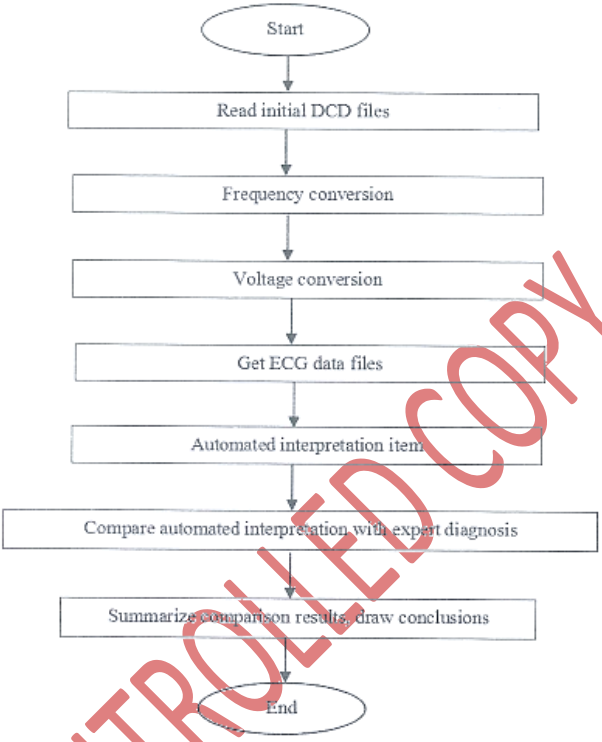
a) without NOISE
b) with high frequency 25uV
c) with 50uV peak to valley sinusoidal line frequency 50Hz/60Hz NOISE
d) with 1mV peak to valley 0.3Hz sinusoidal baseline NOISE

For each of the above NOISE levels, the measurement difference between the NOISE-free ECG and the NOISE ECG must be determined. The two largest deviations from the mean must be estimated before calculating the mean and standard deviation of the difference.

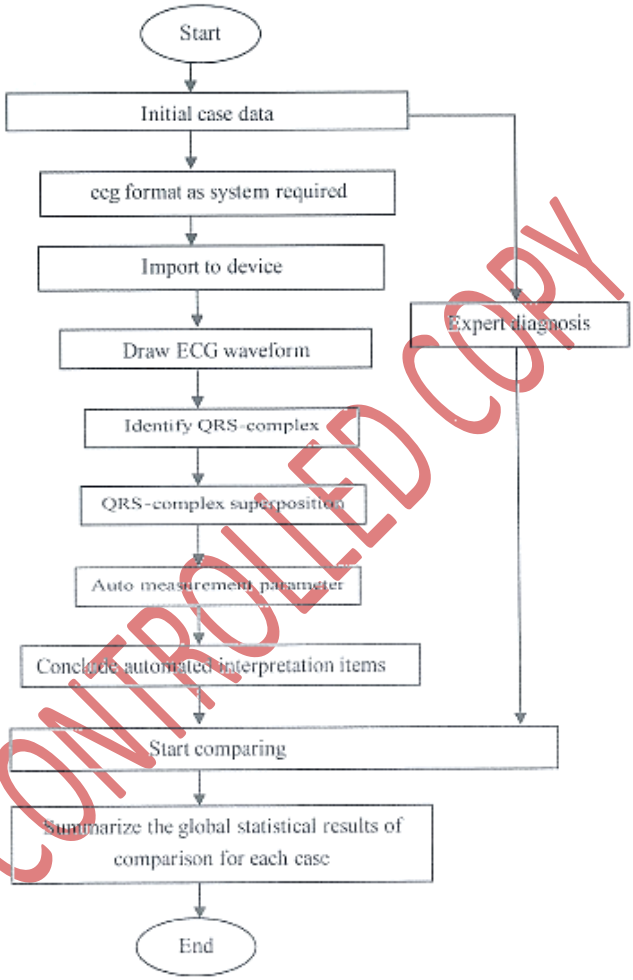
5.2 Verify interpretation function

5.2.1 Verification process

5.2.1.1 CSE diagnostic database



5.2.1.2 Customized database



5.2.2 Verification result

No.	Item	ECGs number	Sensitivity %	Specificity %	Positive predictive value %
1	No abnormal	585	92.01	79.16	97.38
2	Sinus mode Bradycardia	191	96.68	99.73	98.64
3	Sinus mode Tachycardia	78	97.44	96.49	96.90
4	Left atrium Hypertrophy	51	51.09	99.89	81.82
5	Right atrium Hypertrophy	43	42.64	99.66	50.00
6	Dual atrium Hypertrophy	22	93.58	99.14	60.19
7	QRS low voltage	5	96.37	99.36	63.25
8	Cardiac electric axis normal	733	98.36	89.13	98.79
9	Left axis deviation	168	98.65	89.40	98.18
10	Right axis deviation	107	98.23	88.99	94.90
11	Completeness Right Bundle branch block	28	97.00	89.50	95.45
12	Completeness Left Bundle branch block	32	97.73	89.65	91.43
13	No Completeness Right Bundle branch block	41	96.86	89.83	82 35
14	No Completeness Left Bundle branch block	47	94.68	89.83	89.66
15	V1 shows RSR' type	13	90.32	91.14	65.12
16	Left anterior fascicular block	26	91.43	93.25	71.11
17	Left posterior fascicular block	18	89.29	97.37	52.63
18	Left ventricular hypertrophy	236	41.37	92.65	70.36
19	Right ventricular hypertrophy	108	39.75	93.47	65.39
20	I atrioventricular block	13	94.58	91.67	80.64
21	Early anteroseptai MI	10	83.33	99.94	90.91
22	Possible acute forepart anteroseptal MI	27	16.67	98.73	91.89
23	Old anteroseptal MI	26	92.00	98.90	86.47
24	Early anterior MI	77	93.90	88.22	71.96
25	Possible acute anterior MI	10	80.00	99.72	44.44
26	Old anterior MI	13	24.00	99.66	50.00
27	Early extensive anterior MI	24	79.67	99.43	41.18
28	Possible acute extensive anterior MI	16	81.82	99.66	75.00
29	Old extensive anterior MI	30	90.91	88.05	37.04
30	Early apical MI	15	88.32	87.21	88.54

31	Acute apical MI	21	78.12	78.66	53.85
32	Old apical MI	19	79.63	89.94	80.00
33	Early anterolateral MI	36	77.51	79.94	83.33
34	Possible acute anterolateral MI	9	28.57	99.77	33.33
35	Old anterolateral MI	14	70.00	93.60	50.00
36	Early high lateral MI	16	79.65	95.78	80.42
37	Possible acute high lateral MI	8	81.60	99.94	85.71
38	Old high lateral MI	23	81.82	99.66	60.00
39	Early inferior MI	31	88.89	95.00	40.00
40	Possible acute inferior MI	11	76.00	99.60	61.11
41	Old inferior MI	101	96.07	99.24	93.44
42	Early inferolateral MI	73	98.77	96.82	75.94
43	Possible acute inferolateral MI	29	11.11	99.94	50.00
44	Old inferolateral MI	28	84.62	99.83	78.57
45	ST depression, mild anteroseptal myocardial ischemia	7	75.36	99.55	46.67
46	ST depression, mild anterior myocardial ischemia	5	81.24	99.94	33.33
47	ST depression, mild extensive anterior myocardial ischemia	13	79.83	99.13	53.59
48	ST depression, mild apical myocardial ischemia	17	76.97	99.14	43.13
49	ST depression, mild anterolateral myocardial ischemia	25	77.54	99.08	37.64
50	ST depression, mild high lateral myocardial ischemia	21	80.64	99.14	47.39
51	ST depression, mild inferior myocardial ischemia	12	79.73	99.60	55.16
52	ST depression, mild inferolateral myocardial ischemia	20	80.59	99.26	50.61
53	ST depression, anteroseptal myocardial ischemia	4	85.41	99.72	44.44
54	ST depression, anterior myocardial ischemia	12	87.66	98.58	34.85
55	ST depression, extensive anterior myocardial ischemia	7	84.78	98.04	67.75
56	ST depression, apical myocardial ischemia	18	79.95	99.14	55.12
57	ST depression, anterolateral myocardial ischemia	13	87.42	98.97	59.09

58	ST depression, high lateral myocardial ischemia	16	90.06	99.31	57.14
59	ST depression, inferior myocardial ischemia	12	89.88	99.13	40.08
60	ST depression, inferolateral myocardial ischemia	6	91.39	99.16	50.47

Sensitivity: the probability that the "correct Sample" will be determined as a certain "Item" by the auto-interpretation function;

Specificity: the probability that the "Actually Inappropriate Sample" will be determined as a certain "Inappropriate Item" by the automatic interpretation function;

Positive predictive value: the probability that the specified "Inappropriate Item" is "Truly Inappropriate Item".

Appendix II of the EMC Guidance and Producer Declaration

⚠ **Warning**

Use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the Device MANUFACTURER as replacement parts for internal components, may result in an increase in EMISSIONS or a decrease in the ME EQUIPMENT or ME SYSTEM IMMUNITY.

The following cable types should be used to ensure that they meet radiation and interference immunity standards:

No.	Name	Cable length (m)
1	Power cord	1.7
2	ECG lead cable	3.4
3	Potential equalization conductor	3.0

- **Active medical devices are subject to special EMC precautions and must be installed and used in accordance with these guidelines.**
- **Portable and mobile communications radiation equipment may affect the normal use of Medical Devices.**
- **Devices should not be used near or stacked with other equipment, if necessary please observe and verify that they can operate normally in the configuration.**
- **Basic performance: working state stability: Waveform noise and measurement error appearing during measurement are eliminated automatically 10 seconds after eliminating interference, the working state of the device does not change, it can collect and record data continuously, and the waveform does not show obvious changes before and after the test.**

Electromagnetic Emission

<table>
<tr><th colspan="3">Manufacturer's guidelines and statements – electromagnetic emissions</th></tr>
<tr><td colspan="3">This device is intended for use in the electromagnetic environment specified below. The Customer or the user of the Device must ensure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Fulfillment</th><th>Electromagnetic environment - guide</th></tr>
<tr><td>RF Emissions CISPR 11</td><td>Group 1</td><td>The device uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are unlikely to cause any interference to nearby electronic equipment.</td></tr>
<tr><td>RF Emissions CISPR 11</td><td>Class A</td><td rowspan="3">The device is suitable for use everywhere , other than domestic and connected directly to the low-voltage public power supply network of building suppliers used for household purposes.</td></tr>
<tr><td>Harmonic Emissions IEC/EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/flicker emission IEC/EN 61000-3-3</td><td>Fulfill</td></tr>
</table>

Electromagnetic Immunity

Manufacturer's guidelines and statements – electromagnetic immunity			
Devices intended for use in the electromagnetic environment are specified below. Customer or user of the Device must ensure it is used in such an environment.			
Immunity Test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guide**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	κς contact κς air	κς contact κς air	Floors must be wood, concrete or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC/EN 61000-4-4	κς for power supply line κς for input/output line	κς for power supply line κς for input/output line	The quality of electrical power should be like a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	κς line to line κς line to ground	κς line to line κς line to ground	The quality of electrical power should be like a typical commercial or hospital environment.

Voltage drop, small interrupt and power variation on the input line power supply IEC 61000-4-11	<5% UT (>95% UT drop) for 0.5 cycle 40% UT (60% UT drop) for 5 cycles 70%UT (30% UT drop) for 25 cycles <5% UT (>95% UT drop) for 5 seconds	<5% UT (>95% UT drop) for 0.5 cycle 40% UT (60% UT drop) for 5 cycles 70%UT (30% UT drop) for 25 cycles <5% UT (>95% UT drop) for 5 seconds	The quality of electrical power should be like that of a typical commercial or hospital environment. if the user requires continued operation during a power failure, it is recommended that the device be powered from an uninterruptible power supply or battery.
Power frequency (50Hz /60Hz) magnetic field IEC/EN 61000-4-8	3A/m	3A/m	The power frequency magnetic fields must be at the typical site level characteristics in a typical commercial or hospital environment.
Note: UT is the ac mains voltage before the application of the test level.			

Electromagnetic Immunity

Manufacturer's guidelines and statements – electromagnetic immunity			
Devices intended for use in the electromagnetic environment are specified below. Customer or user of the Device must ensure it is used in such an environment.			
Immunity Test	**IEC/EN 60601 test level**	**Fulfillment Rate**	**Electromagnetic environment - guide**
Doing RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communication equipment shall be used no closer to any part of the equipment, including cables, for which the recommended separation distance is calculated from the equation applicable to the transmitter frequency. **Recommended separation distance** $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80MHz to 800 MHz $d = 1.2\sqrt{p}$ 800 MHz to 2.5 GHz Where P is the maximum output power of the transmitter in watts (W) According to the transmitter manufacturer and d is the recommended separation distance in meters (m). The

			field strength of a fixed RF transmitter, as determined by an electromagnetic site survey, a must be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency limit applies.

NOTE 2 This guide may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

a The field strength of fixed transmitters, such as intercept stations for telephone radio (cellular/ wireless) and land cellular radio, amateur radio, AM and FM radio broadcasts, TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the Equipment is used exceeds the applicable RF compliance level above, the Equipment should be observed to verify normal operation. If abnormal performance is observed, additional action may be required, such as changing direction or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, the field strength must be less than 3V/m.

Recommended separation distance between

Portable and mobile RF communication equipment and Devices

The device is intended for use in a device environment where emitted RF interference is controlled. The customer or user of the device can help prevent device interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.

Transmitter's maximum output power rating (W)	**Separation Distance According to Transmitter Frequency(m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{p}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{p}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{p}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

For transmitters rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the transmitter frequency, where P is the maximum output power level of the transmitter in watts (W) according to transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the higher frequency limit applies.

NOTE 2 This guide may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

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